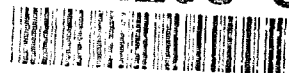


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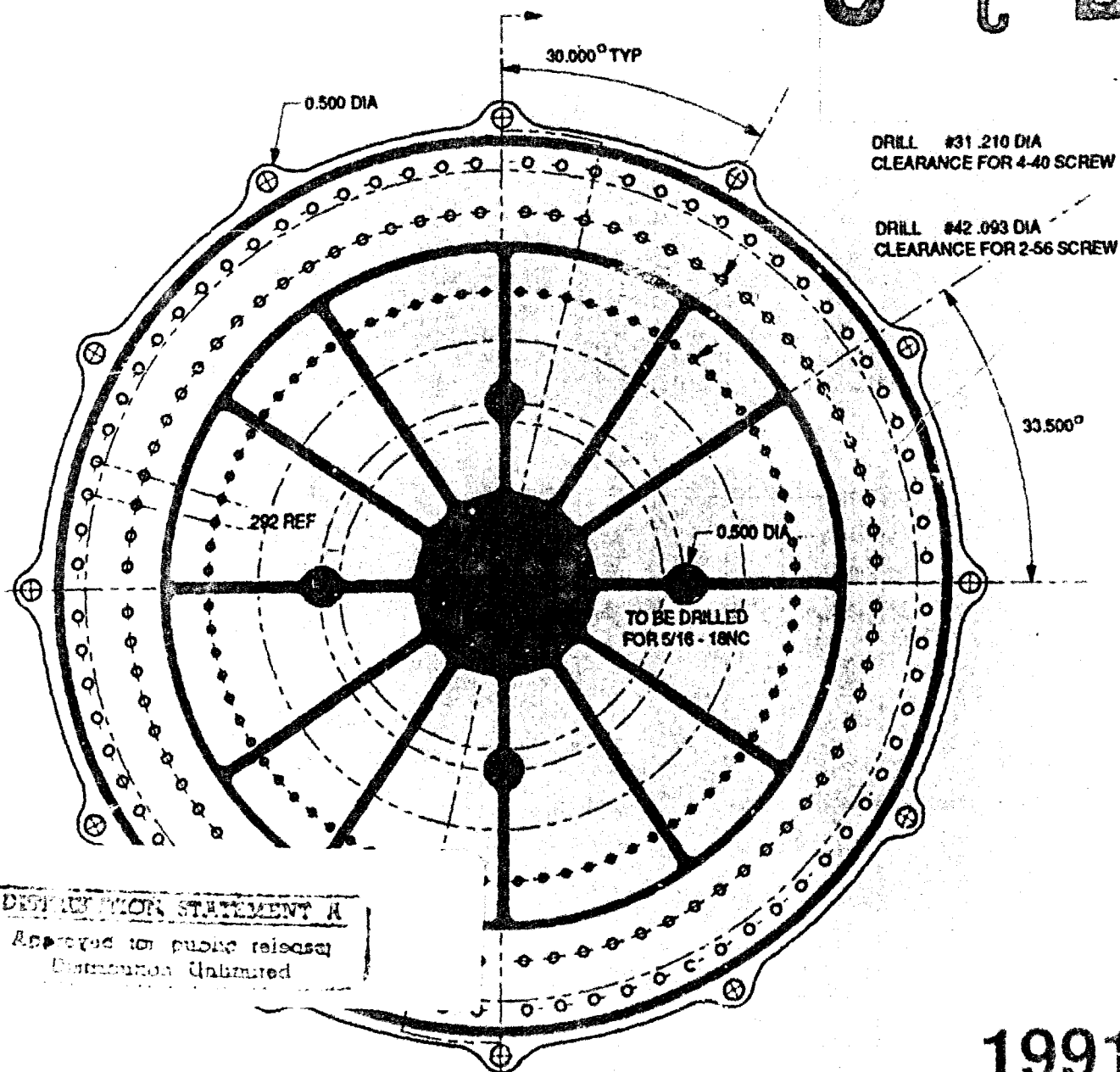


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ON THE COVER

Research and development carried out at the Department of Veterans Affairs Atlanta Rehabilitation Engineering Unit is featured on the front cover. The mechanical drawing describes the outer housing of a curvilinear synchronous motor for a wheelchair drive mechanism. The motor uses rare-earth magnets in a disc-shaped rotor to produce high torque at low motor speeds. The rotor is sandwiched between stator pole-pieces fastened to each outer housing "shell" shown in the drawing. Two of these shells fasten together to form a motor housing. The housing is cast aluminium, which reduces the overall weight. The back iron is significantly reduced by a proprietary design process to further reduce the weight. The outer shell has receptacles to hold the main bearings; one on each side. An insert in the outer edge provides access for electrical connection and control circuitry. The Progress Report related to this topic is on page 436.

Mechanical drawing for the cover courtesy of VA Atlanta Rehabilitation Engineering Unit. Cover design, illustration, and production: Frank Vanni, Department of Veterans Affairs Rehabilitation Research and Development Center, Baltimore, MD.



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- 475 Skin-CNS-Bladder Reflex Pathway for Micturition After Spinal Cord Injury
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- 532 Treatment of Pressure Ulcers
- 533 Analytical Service Demonstration of the Role of Biochemical and Behavioral Indicators in the Prevention of Recurrent Pressure Sores

- 534 Treatment of Pressure Ulcers by Electrical Stimulation
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- 548 National Invitational Conference on the Development of a Health Services Research Capacity in Physical Disability and Rehabilitation
- 549 Trauma and Disability Outcomes (TDOS)
- 550 Rehabilitation Technology Training: A Plan for Facilitating the Delivery of Technology
- 551 Transferring Technology from the Research Laboratory to the Commercial Market
- 552 Implementation and Follow-Up of Rehabilitation Technology
- 553 Electromagnetic Effects on Bone Tissue and Its Chemistry
- 554 Application of Microcomputer Alternate Access Methods to Music Composition and Education
- 555 Social Security Administration Voluntary Rehabilitation Demonstration Project
- 556 Social Security Pain Assessment Instruments Development Project
- 557 Project Network
- 558 Social Security Administration Research Demonstration Program (RDP)
- 559 Health Insurance Coverage of Disability Beneficiaries
- 560 Transportation Information Base: People with Disabilities

I. Amputations and Limb Prostheses

A. General

[1] Toward Better Methods of Nerve Repair and Evaluation

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Sponsor: VA Rehabilitation Research and Development Service (Project #B003-5RA)

Purpose—The goal of this research is to provide a means for repair of nerve function. This includes cases of nerve injury within intact limbs, connection of nerves in an amputation stump to a prosthetic limb, and functional neuromuscular stimulation (FNS) applications in spinal cord injury. It is felt that all of these modes of nerve repair can be achieved using a general-purpose neural interface, capable of recording from, and stimulating small groups of, axons that have regenerated through holes in the device.

Methodology—Initial work focused on demonstration of the technology. Passive neural interfaces were implanted in the peroneal nerves of 12 Sprague-Dawley rats and evaluated at one-year postoperatively. The regenerated nerves were successfully recorded from and stimulated electrically using these devices. The current focus of the work is on refinement of the technology and on optimization of the design of the neural interfaces in terms of biocompatibility. Refinement of the technology is being carried out in three major areas: 1) development of improved means of coupling the neural interfaces to the nerves; 2) development of suitable technologies to make electrical connections to the implanted neural interfaces; 3) development of improved passive versions of the neural interface; and, 4) development of the microelectronic circuit blocks required to include on-chip signal processing in future devices. Toward optimization of the physical design, a new study using 30 neural interfaces of varying "via hole" sizes and densities

is nearly completed. The purpose of this study is to determine the effects of varying the size and spacing of the via holes on the histological and electrophysiological characteristics of the regenerated nerve.

Progress—A new surgical coupler has been developed and tested *in vivo* and shown to overcome major limitations of the previous, precast couplers. Most notably, the new couplers are directly bonded to the silicon surfaces, eliminating the various unwanted channels (for axons to regenerate around the neural interface) that are inevitably present when the precast couplers are used. Various types of suitable interconnect cables have been fabricated. An entirely new set of designs for passive neural interfaces, taking advantage of information obtained from the previous *in vivo* work, have been fabricated and are now being implanted. Microelectronic circuit blocks to carry out on-chip signal processing have been implemented using the Stanford BiCMOS process. The present study toward optimization of the physical design of the neural interfaces is nearly completed, with electrophysiological testing of the implants (10 months postoperatively) completed, and histological results pending.

Results—The new surgical coupler designs were seen to provide greatly improved characteristics both surgically and physiologically. Two types of interconnect cables have been fabricated and are being tested in electrically-biased long-term soak tests in

various ionic media. Teflon-coated gold microcables have performed extremely well over many months of soaking and photolithographically-fabricated versions are now being evaluated under the same conditions. The new passive devices are being outfitted with implantable electrical interconnect cables. The active microelectronic circuit blocks mentioned above have been successfully fabricated and are now being tested. All of the neural interfaces implanted in the optimization study have been evaluated electrophysiologically and data collected which indicate that for most of the designs, many electrophysiologically viable axons regenerated through the neural interfaces.

Future Plans—To successfully realize directly interfaced limb prostheses, an advanced version of the neural interface with on-chip signal processing circuitry is required. Work currently underway will

combine the results of the optimization study with design refinements to realize the first implantable version of the neural interface which contains such circuits and includes microcable interconnections to external circuitry.

Recent Publications Resulting from This Research

- Accurate Small-Signal Characterization of Microelectrodes. Kovacs GTA, et al., in Proceedings of the 13th Annual RESNA Conference, Washington, DC, 381-382, 1990.
- Development of a Neural Network Interface for Direct Central Nervous Control of a Prosthetic Limb. Wan EA, et al., in Proceedings of the International Joint Conference on Neural Networks (presented as a plenary paper), Washington, DC, 1990.
- Technology Development for a Chronic Neural Interface. Kovacs GTA, PhD diss., Technical Report No. E073-1, Stanford University, 1990.
- Regeneration Microelectrode Arrays for Direct Interface to Nerves. Kovacs GTA, Digest of Technical Papers: Transducers '91, 116-119, New York: IEEE Press, 1991.

[2] Viscoelasticity of the Limb in the Compartment Syndrome: A Pilot Study

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Sponsor: VA Rehabilitation Research and Development Service (Project #A90-98AP)

Purpose—In the compartment syndrome, ischemia within a closed space leads to a continuing cycle of increasing pressure and further ischemia. The compartment syndrome is a serious limb-threatening condition which affects members of the aging veteran population. Surgical correction of embolectomy and primary vascular thrombosis, as well as elective bypass surgery, can leave the patient at risk for reperfusion injury and the compartment syndrome. A related problem is primary deep vein thrombosis which can lead to phlegmasia cerulea dolans, a limb-threatening and often fatal complication. Less common causes are trauma, bleeding due to anticoagulant therapy, and application of external casts or splints.

Methodology—Our aim is to test a new noninvasive method for measuring viscoelasticity of the limb that can replace or supplement direct and invasive compartment pressure measurements. The new procedure has been examined in laboratory studies. We

wish to investigate the usefulness of this test procedure as a clinical, noninvasive screening method to diagnose the presence of the compartment syndrome and related edematous swelling within the limbs, and to follow the course of viscoelastic changes during treatment. At least 10 patients from the VA Medical Center, Castle Point, NY, are to be included. As part of the data analysis, noninvasive viscoelastic measurements will be compared with directly measured compartmental pressures. Regression analysis will be utilized to provide a functional relationship between viscoelastic parameters and the directly measured pressure. Confidence intervals for regression parameters will be determined.

Progress—In work to date, the modeling of the viscoelastic behavior has been examined in further detail over the cycle of pressure loading and unloading soft tissue. Instrumentation for measuring viscoelasticity is being readied for clinical testing.

[3] Feasibility of Green/Red/IR PPG in Assessing Ischemic Tissue Survival: A Pilot Study

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Sponsor: VA Rehabilitation Research and Development Service (Project #A89-25AP)

Purpose—This study is examining optical skin reflectance in the presence of soft tissue ischemia using multiple light wavelengths. Ischemic conditions are encountered in interventions to close open wounds. These can occur in treatment of pressure ulcers, tissue necrosis associated with vascular disease, and following trauma. The ischemia, when unrecognized, can lead to unexpected death of soft tissue in the closure area. Fluorometry and a variety of other methods are available for perfusion assessment. However, there is a need to consider methods which might provide totally noninvasive measurements. Studies of the optical properties in soft tissue have prompted the need to investigate skin reflectance spectrophotometry for evaluating ischemia and flow obstructions.

Methodology—The methods are an extension of principles employed in photoplethysmography and pulse oximetry. Data are acquired on skin reflectance at multiple light wavelengths (red, green,

infrared), including both mean and pulsatile components. Preliminary data are being obtained from both animal studies in a surgical flap model and from human studies with postsurgical patients. The data will be correlated with tissue outcomes and examined in the context of a photon diffusion model for soft tissue.

Preliminary Results—In ten laboratory studies, light reflectance in a surgical flap model has been examined in relation to tissue viability. Measures of tissue congestion were consistent among trials. The mean reflectance in general were not as predictive of flap survival as were the previous fluorometric flowmetry studies.

Recent Publications Resulting from This Research

In Vivo Reflectance of Blood and Tissue as a Function of Light Wavelength. Cui W, Ostrander LE, Lee BY, IEEE Trans Biomed Eng 37:632-639, 1990.

[4] Transplantation of Limbs for Amputees : A Pilot Study

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Sponsor: VA Rehabilitation Research and Development Service (Project #A90-6AP)

Purpose—The purpose of this project is to establish the experimental foundation for the reconstruction of limb and major composite tissue defects with allografted tissues.

Patients with limb amputations must either function without the use of their limb, or must compensate for this limb loss with a prosthesis. Although prostheses are very useful, they fall short of providing the function of a normal or replanted limb. Allograft limb transplantation may provide a solution to the problem of limb amputations where

the amputated limb cannot be salvaged for replantation. Donor limbs could be used to replace missing limbs through microsurgical transplantation.

The VA provides care to a large number of patients with limb amputations. A significant number of these are upper extremity amputees; some are bilateral amputees. The bilateral upper extremity amputee suffers the greatest from limb loss. Composite tissue allografts will become important in limb salvage operations (i.e., resection for Ewings sarcoma). The transplantation of upper limbs to an

amputee could provide significant function if the toxicity of immunological suppression could be minimized or eliminated. Present microsurgical methods provide the necessary technical skills to transplant lower limbs. Further work is underway to decrease the toxicity of immune suppression with cyclosporin-A. The use of anti-CD4 monoclonal antibodies may produce sufficient immunosuppression without significant toxicity, allow limb transplants in nonhuman primates, and eventual clinical trials of limb transplantations in humans.

Replantation of amputated limbs provides useful function. However, in many cases the limb cannot be salvaged because of the severity of the injury, or if the condition is secondary to tumor invasion or other nontraumatic disease processes. In these cases the amputee must rely on a prosthesis for function. The ultimate significance of this research would be to provide transplanted limbs for patients with amputations to improve their level of function and quality of life. This can only be accomplished by improving our methods of preventing rejection

without undue risk to the patient. We would, therefore, study a new group of medications (anti-CD4 monoclonal antibodies) for preventing limb rejection and minimizing or eliminating long-term secondary drug effects.

Progress/Methodology—We are presently studying limb transplantation across major histocompatibility barriers in rats in an attempt to modulate the immune system with monoclonal antibodies. The study involves the transplantations of rat hind-limbs to a corresponding recipient. Major histocompatibility barriers will be crossed. Survival function and long-term growth will be followed by clinical examination, necropsy, and histopathology. Data will be analyzed to characterize the course of composite tissue allografts.

Implications—These findings will serve as a guide for developing similar composite tissue transplants in nonhuman primates.

[5] Computerized Methods for Prosthetics and Orthotics

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Sponsor: National Institute on Disability and Rehabilitation Research

Purpose—We are involved in several projects meant to bring the power of computer methods to prosthetics and orthotics. Principally, we felt computer technology would initially have the most impact on prosthetics and orthotics in the areas of modeling and processing of body structures.

Progress—Structural Modeling: Finite-Element Modeling. Work previously reported has involved the use of finite element analysis (FEA) to understand the mechanics of an above-knee (AK) amputee's limb during stance. Experiments using Kulite diaphragm strain gauge transducers were conducted to measure surface pressures at key locations to validate the computer models. While we know the transducer (designed for hydrostatic situations) to be linear and repeatable from test to test, its performance at the interface between limb and socket is not well documented. Bench tests are under

way to quantify the measuring capabilities of the transducers.

The material used in these bench tests must have characteristics similar to those of soft tissue so as to best simulate the experimental conditions of our prosthetic socket studies. The material chosen is Sylgard 527 (Dow Corning). Cylindrically-shaped samples were made 3 inches in diameter and 5 inches high.

The following setups are being investigated: 1) uniaxial compression on samples whose edge is free and on samples whose edge is restricted; and, 2) loading/unloading of an indenter at the center of samples, both free and enclosed cases. Comparisons of pressures both measured and predicted by FEA will be made with the theoretical solution of each bench test configuration in order to quantify the performances of the transducers and the computer modeling techniques.

Structural Modeling: Determination of Centers of Rotation. The Maximum Likelihood method was deemed unsuitable for use in a practical setting due to its complexity. It required the numerical computation of a double integral of a very sharp exponential function, which made it unstable. Moreover, the improvement it provided over other methods examined was marginal.

The other methods (Least-Squares and Generalized Reuleaux) were extended to take advantage of multiple markers. A complete set of functions for approximating their behavior under noise was found. These equations allow the user to determine the approximate bias and variance of the estimated center of rotation for a given experimental setup. When enough markers are available, the fact that they are mounted on a rigid body can be used to improve the estimation of the center of rotation. This feature was introduced into both methods.

Structural Modeling: Kinematic Identification of Reference Axes. A reference axis for the knee can be described based on the geometry of the posterior femoral condyles which are spherical, or wheel-like, in shape and the mating articular geometry of the tibia which is nearly planar. Just as an axle exhibits the simplest motion for a rolling wheel, an axle of the knee exists which exhibits the simplest motion of the flexing knee. An axle remains a fixed distance above the roadway regardless of whether the wheel is rolling, sliding, or both. The knee joint moves in a

combined rolling and sliding motion and this property can be used to help identify the position of the knee axle.

A computerized routine was developed which allows the location of the knee reference axis to be determined from measured motion of the knee joint. In solving the problem, we view the motion of the knee as if the femur (wheel) were fixed in space and the tibia (roadway) was moving under it.

Structural Processing: Automated Finite Element Mesh Generation. The Bone and Prosthesis Modeling Software Suite developed by the Cornell University Biomechanics Group for designing total joint components has been installed. For application to prosthetics, the geometries of both tissue and bone need to be identified. From an AP scout view, a transverse scan is selected and digitized twice; producing a bony and tissue surface geometry. We found that applying a median filter to the image followed by thresholding across the desired boundary is adequate to efficiently identify each edge. The thousands of bone and tissue surface points are written to files.

Software was developed which aligns the two surfaces and identifies either 36, 72, or 144 points along each boundary of every level from which to create a finite element model. These points are then imposed over an existing finite element cylindrical mesh to create the model of the limb to which initial socket boundary conditions applied.

[6] Resource Unit for Information and Education

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—The Information and Education Resource Unit assists consumers, academicians, and service providers in locating information about prosthetics/orthotics management and the disabling conditions which look to prosthetic/orthotic solutions. The Unit *collects* information, assembling it in databases; *disseminates* information via a telephone help-line; and *generates* new information by sponsoring educational opportunities and publishing informational documents. The Unit does not endorse or recommend any product, service, or clinician;

however, the philosophy of the Resource Unit is that information provides support.

Progress—All databases currently contain over 1,000 entries related to prosthetics, orthotics, and disabling conditions. These entries include information on: amputation management, amputee support groups, state-of-the-art research, general disabilities, recreational resources, self-help groups, nursing care, prosthetic/orthotic schools and service providers, relevant prosthetic/orthotic publications, and

manufacturers' information. New information on prosthetic/orthotic research, products, and services is being collected as these are being reviewed by the Unit. This information is added to the databases and made available to the public.

The help-line, available on (312) 908-6524, disseminates information in the databases to the many callers contacting it monthly. Additionally, by delving into alternative resources, the help-line directs callers to other information clearinghouses or professionals which may be better able to service their request. Follow-up occurs via telephone or correspondence where the caller receives written confirmation of their request and accompanying materials if available. No charge is made for any help-line service.

Consumer feedback is formally acquired through yearly meetings of the Consumer Advisory Panel of the Rehabilitation Engineering Program. Educators and clinicians have benefitted from their invited attendance at these meetings. The Panel, consisting of persons with disabilities managed by prosthetic/orthotic solutions, met at the Rehabilitation Institute of Chicago, Chicago, IL this year for a series of presentations made by Panel and laboratory members, and for the yearly business meeting.

This year marked the advent of several publications describing laboratory activities including: *Capabilities*, a quarterly newsletter; the 1990 Annual Report; the Resource Unit promotional brochure; regular brochures describing laboratory activities; and others. These publications are available free of charge to those contacting the laboratory.

[7] Prosthetic/Orthotic Materials

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Purpose—Standardized testing modalities are being used to characterize the composition, structure, and performance of the current armamentarium of prosthetic and orthotic polymers prior to and after fabrication, after weathering, and after liquid nitrogen quenching. Also, new thermoplastic elastomeric materials plus fiber-reinforced composites are being examined for their potential for providing improved prosthetic and orthotic devices.

Progress—This year, the multi-faceted approach to materials investigations of orthotic and prosthetic polymers has progressed in four specific areas: 1) continued investigation of the effects and mechanisms brought about by accelerated weathering, and thermal treatments to counteract these effects; 2) continued structural identification and establishment of database of Fourier transform infra-red (FTIR) and nuclear magnetic resonance (NMR) spectroscopies in the as-received and after clinical forming procedures; 3) new developments and testing of novel polymethylmethacrylate (PMMA) and carbon fiber (CF) composites; and, 4) preliminary wear

studies on a new class of materials, namely, thermoplastic elastomers (TPEs).

Results—*Polymer Degradation*. The crystallinity of Subortholen® was measured by a Perkin-Elmer differential scanning calorimeter (DSC-2). By comparing their heat of fusion (ΔH) to that of a 100% crystalline polyethylene, the degree of crystallinity of each sample was determined. The crystallinity attained a maximum value of 72% following 5 weeks of accelerated weathering. The liquid nitrogen quenched material had a 48% crystallinity while the as-received samples had 59%. The increases in the percent crystallinity resulted from the decomposition of polyethylene amorphous structure and were accompanied by a decrease in mechanical ductility. In addition, the decomposition of amorphous structure has its greatest tendency to occur on the surface of a sample.

Changes in crystallite size were noted with a Philips X-ray diffractometer (XRD). The decreased *sharpness* of the X-ray diffraction peaks indicated that the crystallite size of the as-received Subortholen® was reduced by the liquid nitrogen

quenching treatment. Also, the crystallite size of polyethylene was prone to grow during weathering.

Polymer Identification. Structural identification of five commercial prosthetic and orthotic polymers have been completed via Fourier transform infra-red (FTIR) and nuclear magnetic resonance (NMR) spectroscopies in both the as-received condition and after simulated clinical processing. Identifications included poly(ethylene terephthalate), polyethylene plus coloring agents, polypropylene, copolymers of polyethylene and methacrylic acid, and cellulose acetate butyrate.

Significant changes in the spectra occurred after simulated clinical processing. These changes included increases in the (OH) concentration for some of the polymers, shifts of peak positions, and changes in peak shape reflecting changes in the crystallinity of the polymers. New peaks also suggested the formation of decomposition by-products.

PMMA/Carbon Fiber Composites. Matrix, fiber, and interphase properties are being explored to optimize fatigue performance. The biocompatibility requirement excludes traditional composite materials such as epoxies and silane sizing agents. Therefore, polymethyl methacrylate and polycarbonate (PC) are the matrix materials under study, while carbon fibers are being used as reinforcement.

Solution forming, a novel approach to carbon fiber incorporation into acrylic matrices, has demonstrated PMMA/CF composite strengths on the order of 10 to 20 times of bulk acrylic.

Wear of TPEs. Wear tests of three thermoplastic elastomers (brand name C-Flex) were carried out on a Taber Model 503 Abraser. For the three C-Flex materials of Durometer A hardness of 35, 40, and 75 there appeared to be a direct correlation between hardness and resistance to wear.

Future Plans—Research is now focused on controlling the performance of the current prosthetic/orthotic polymeric armamentarium through heating and quenching treatments. It is also focusing on the newer composites and TPEs.

Recent Publications Resulting from This Research

The Degradation Mechanisms and Toughening Technique for Polyethylene Biomaterials. Chiu C, Healy K, Lautenschlager E, in Transactions of the Society for Biomaterials, Scottsdale, AZ, 213, 1991.

High Strength PMMA Fibers for Use in a Self-Reinforced Acrylic Cement. Buckley CA, Lautenschlager EP, Gilbert JL, in Transactions of the Society for Biomaterials, Scottsdale, AZ, 45, 1991.

Manipulating Structure, Property, and Performance of Polyethylene Polymers. Chiu C, presented at the Northwestern University Dental School Centennial Conference, Chicago, IL, 1991.

B. Upper Limb

1. General

[8] Direct Muscle Attachment as a Control Input for a Position-Servo Prosthesis Controller

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Purpose—The purpose of this study is to determine whether direct muscle attachment, in the form of tunnel cineplasty or otherwise, will provide superior prosthesis control compared to that possible with conventional methods. Surgical intervention is necessary to provide direct muscle attachment to prostheses. Tunnel cineplasty is an example of a procedure

used to bring a muscle force outside the body with which to power and control a prosthesis. The procedure involves the construction of a skin-lined tunnel, by way of skin grafts, through a belly muscle. Developed by Sauerbach in 1916, the procedure fell out of favor in the USA during the late 1950s due mainly to the failure of a significant

number of tunnel cineplasties to provide sufficient force and excursion with which to power a prosthesis. But the excellent control properties the procedure provided, and continues to provide, is well documented.

We believe that a miniature tunnel cineplasty, used as a servo actuator in conjunction with an extended physiological proprioception (EPP) type controller can significantly improve the control of prosthetic devices for upper limb amputees. Under these circumstances, the problem of sufficient power would no longer be a complication since it would be provided by an external source. The sensory feedback that is inherent in both the skin of the tunnel and the stretch receptors of the cineplastized muscle provide a means with which to convey proprioceptive information on the state of a prosthesis to its user in a somewhat natural manner.

The use of multiple miniature tunnel cineplasties in conjunction with EPP controllers opens up a whole new realm of possibilities. The use of a number of forearm miniature tunnel cineplasties, each with an EPP controller, has the potential to provide independent multidigit control for below-elbow amputees or, in the case of high-level upper limb amputees, the use of a number of miniature pectoral cineplasties could be used to

augment or replace existing control sites to provide improved multifunctional control of arm prostheses.

Methodology—We propose to perform pursuit tracking studies and blind positioning studies with tunnel cineplasty subjects in order to quantify the performance possible with this control methodology and also to try and quantify the proprioceptive feedback component of the total sensory feedback. The transinformation rate is the performance index that is to be used to provide a measure of performance. The higher the transinformation rate, the better the performance of the system under test.

The position, velocity, and force controllability that people have through their cineplasties are being investigated. This data, when compared with data of previous studies, should provide insight into whether or not the surgical intervention required for these miniature tunnel cineplasties can be justified in terms of superior performance.

Progress—Work done to date: writing of software to process the data and to run the experiments; design, construction, and characterization of the instrumentation required for the experiments; and location of subjects with tunnel cineplasties who would be prepared to participate in the research.

[9] Evaluation of Lower Limb Amputees for Functional Prosthetic Use: The Role of Objective Cardiac Testing

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Purpose—This pilot study proposes to evaluate the efficacy of a defined protocol for the screening of patients prior to prosthesis prescription and gait training. The protocol will focus on the identification and treatment of cardiac dysfunction, particularly occult myocardial ischemia and/or arrhythmia, that might preclude successful and safe gait training. Currently available noninvasive cardiac testing modalities will be used.

Methodology—The plan is to objectively evaluate

the cardiac status of 50 consecutive new amputees during their prosthetic training with a temporary limb. Each patient will receive a complete history and physical examination by a physiatrist and cardiologist. Patients will then undergo a defined cardiac evaluation consisting of ambulatory ECG recording, arm ergometry radionuclide exercise testing, and coronary vasodilator radionuclide imaging.

Contemporary ECG recorders can accurately document ST segment displacement as evidence of silent or symptomatic ischemia, as well as cardiac

arrhythmias. Two ECG channels will be recorded for 24 hours, approximately in the horizontal and vertical axes. The patient will be asked to maintain a diary of all symptoms (chest discomfort, dyspnea, palpitation, etc.) and significant activities, including rehabilitation therapy sessions.

Cardiac function will also be evaluated by arm ergometry radionuclide exercise testing and vasodilator radionuclide imaging. Arm ergometry radionuclide exercise testing is an alternative to treadmill exercise testing for patients such as amputees who cannot perform lower extremity exercise, and vasodilator radionuclide imaging is an alternate for deconditioned amputees who cannot perform either upper or lower extremity exercise.

Radionuclide exercise testing will assess the capacity of the patient for physical work, as well as evaluate for evidence of occult coronary artery disease as manifested by activity-induced myocardial ischemia and arrhythmia. Vasodilator radionuclide imaging will use intravenous dipyridamole to increase coronary artery blood flow (similar to exercise) to assess myocardial perfusion. Technetium-99m isonitrit perfusion studies will be interpreted by two experienced physicians to determine the extent, distribution, and severity of any exercise-induced myocardial ischemia.

Progress—To date, three subjects have completed the protocol. Experimental testing should be completed by December, 1992.

Results—The above tests will be used to determine: 1) the number of patients in whom any element of the baseline evaluation reveals evidence of previously unsuspected cardiac dysfunction; 2) the value of baseline arm ergometry radionuclide exercise testing versus vasodilator radionuclide imaging to detect occult myocardial ischemia, as compared with the incidence of ischemia disclosed by ambulatory electrocardiography in these patients; 3) the relation of the above findings to subsequent completion of prosthetic gait training. Patients with ischemia may be referred for further cardiologic evaluation and therapy, which would allow completion of rehabilitation; 4) the relation of ischemia during gait training, evident either by symptoms or ambulatory electrocardiography to that suggested during screening (i.e., the "sensitivity" and "specificity" of the screening test); 5) the relationship of "occult" (ambulatory ECG only) to symptomatic (angina pectoris or equivalent) episodes of myocardial ischemia during both baseline recordings and records during rehabilitation; 6) the occurrence of cardiac arrhythmias during baseline and gait training recordings and their relationship to successful gait training (i.e., predictive value); 7) the relation of arrhythmia to ischemia, either concurrent or nonconcurrent, or to other cardiac abnormalities; and, 8) the relationship of arrhythmia to symptoms.

[10] Objective Assessment of User Interface Control Strategies for Proportionally Controlled Prostheses and Orthoses

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Purpose—A number of proportionally controlled prosthetic and orthotic devices are available for the rehabilitation of individuals with various upper-limb disabilities; powered prosthetic arms for amputees are the most common and are commercially available. As these devices proliferated, so did the number of strategies for interfacing amputees to their devices. Since no objective comparative performance evaluation of interface control strategies has

ever been done, the choice of an appropriate strategy for an individual is difficult to make. This project aims to develop a laboratory system which will facilitate the objective evaluation of an individual's performance in reaching and grasping tasks using any interface control strategy to control a wide range of assistive devices. It also aims to use this tool to compare the performance of several common interface strategies, and answer the follow-

ing questions: 1) Is the laboratory system a reliable tool for objectively assessing the performance of a prosthetic or orthotic device? 2) Of the commonly used interface control strategies, which are the best performers? How significant is the performance between strategies? and, 3) To perform well, what features should an interface control strategy have?

Methodology—The system has been designed so that the full range of command source transducers and prosthetic or orthotic devices can be tested. At the heart of the system is a software program called the Interface Strategy Management System (ISMS). The ISMS selects the appropriate strategy modules required to implement a particular interface strategy, and uses these modules to process the command sources and feedback from the prosthesis or orthosis. The processed information is then presented as a positional command to the assistive device.

In the assessment phase of the project, the laboratory system will be used in the evaluation of four common user-interface control strategies. Initially, the command source will be a 2-axis joystick controlled by shoulder movement. The assistive device will be a powered prosthetic arm with an electric hand and electric elbow. The subject will be asked to reach for an object, grasp it, and place it on a target. The target and object will be placed automatically in different work planes under computer control. The test aims at evaluating the ability of the user to integrate prehension/release of the prosthetic hand, flexion/extension of the prosthetic elbow, and movement of the intact shoulder. The performance of each of the interface strategies will be measured according to the following criteria:

1. *Reaction Time*. This is the time from the placement of the target and object until the subject begins to move the prosthetic limb. It is hypothe-

sized that reaction time will indicate the amount of conscious planning required to use the strategy.

2. *Total Time to Complete the Task*. It is hypothesized that this time will indicate the feasibility of integrating the strategy into a functional activity. A total of 20 nondisabled subjects will participate in the study. Five subjects will be randomly assigned to each of the following four strategies: *Velocity Control*. Elbow flexion and hand opening will be proportional to vertical shoulder velocity. Elbow extension and hand closing will be proportional to horizontal shoulder velocity. The subject will use a quick jerk of the shoulder to switch between hand and shoulder control. *Positional Control*. The vertical joystick axis will be proportional to elbow position and the horizontal axis to hand position. The prosthesis will lock if the shoulder is motionless for one second and unlock if shoulder excursion passes the locked position. This is similar to the strategy used by the Utah Artificial Arm. *Impedance Control*. Joint stiffness will be proportional to the sum of signals from the two joystick axes. The velocity of the joint will be defined as velocity control. *On-Off Control*. In this strategy, the user either moves the elbow or hand at full speed or keeps them stationary. No intermediate speeds (proportionality) are allowed.

The entire assessment procedure will be repeated using an EMG command source. The vertical joystick axis will be replaced by biceps EMG and the horizontal axis will be replaced by triceps EMG.

Progress/Results—The software development phase of this project is complete and a fixture for mounting an above-elbow prosthesis on able-bodied subjects has been built. The assessment phase is in progress and no results are available at the present time.

[11] Functional Biomechanical Characterization and Functional Design Specification: Upper-Extremity Prosthetics, Hand Function Differentiation

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Sponsor: National Institute on Disability and Rehabilitation Research

Purpose—Within the area of enhancing the approach trajectories and alignment of prehensors

relative to objects to be grasped, we have several objectives. One is a study of the division of function

between the dominant and nondominant physiological hands. This study, part of a broader investigation of reaching and prehensor guidance during object acquisition, may lead to a better understanding of the use of a prosthetic prehensor in a nondominant role, assisting an intact dominant physiological hand.

Progress—This study (within our investigation of "Reaching and Prehensor Guidance") is nearing completion. During the past year, we have completed videotaping of all 12 subjects performing each of the four selected bimanual activities—preparing and eating a breakfast, writing a check and preparing it for mailing, assembling a picture frame, and dressing. The videotapes have been analyzed to produce: 1) sequential listings of the actions performed during the activity; 2) the static and dynamic prehension patterns used by both the dominant and nondominant hands; and, 3) the gross orientation of the elbow and wrist, in conjunction with a prehension pattern, at 5-second sample intervals.

From the videotape analysis, the data are being reduced to identify differences in the utilization of the dominant and nondominant hands. Of particular interest are characteristics in the utilization of the nondominant hand which could be incorporated in the design of prosthetic prehensors. This is of interest because of the widely held expectation,

based on practical considerations, that a person with a unilateral amputation will use a prosthetic prehensor as a nondominant "hand," regardless of the pre-amputation dominance.

The identification of static prehension patterns is based on the classification of Kamakura. In this classification, patterns are described as being within one of four major types: power, intermediate, precision, and no thumb—each of which is further divided into more specific forms.

An initial analysis of the occurrence of prehension patterns (normalized, for a given activity, to permit averaging across subjects) indicates that the precision prehension pattern type was used most often by both hands in all four activities. In the breakdown of patterns within a type, the "parallel mild flexion" pattern was used most frequently by both hands in every activity. This pattern was consistently selected for use in at least 30% of the actions of each hand, regardless of activity.

In considering the role of the nondominant hand, it is notable that the *nondominant* hand was engaged in some kind of prehensile activity for most of the instances of action. This observation does not support the notion that the nondominant hand functions primarily for nonprehensile purposes. An implication of this observation is the importance of providing active prosthetic prehensile function to persons with unilateral arm amputations.

[12] Functional Biomechanical Characterization and Functional Design Specification: Upper-Extremity Prosthetics, Approach Trajectories

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—Within the area of enhancing the approach trajectories and alignment of prehensors relative to objects to be grasped, we have the following objectives: 1) design of a *powered humeral rotator* to extend the spatial envelope in which a prehensor can be actively positioned by a person with an above-elbow or higher level of amputation; and, 2) development of a *computer-based prehensor positioning assessment* tool to aid prosthetists in the selection of components for

clinical applications, especially for fitting higher level and bilateral amputations.

Progress/Preliminary Results—*Powered Humeral Rotator*. The mechanism consists of two gearmotors driving (in parallel) an internal gear attached to the elbow baseplate. A third gearmotor provides locking through a worm gear transmission to the drive shaft of one of the driving gearmotors. When all three gearmotors are energized, the rotator moves. When

the gearmotors are off, the rotator is locked against external rotation by the worm gear arrangement.

The concept behind the power-drive design is to build an efficient system and simple mechanism, but one that cannot be backdriven. We would prefer not to use a separate backlocking mechanism. We also want a low profile. The multiple motor approach was decided upon: use a simple and efficient gear reducer (spur gears) for most of the power going through the gear reducer but have an inefficient pathway that carries low power. The first prototype works but we do not know if it works as intended and at the efficiency desired. We are working on understanding the prototype mechanism, planning to find ways to maximize the efficiency.

Computer-based Prehensor Positioning Assessment. The goal of this project has been the development of a software tool that will assist prosthetists in the visualization of complex arm prostheses as a basis for comparing the effectiveness of different arrangements of prosthetic components. The practical implication of the software tool is the potential to reduce the time and effort presently involved in working toward a functionally appropriate prosthesis configuration, especially for persons with high-level and bilateral arm amputations. It is proposed that the current practice of constructing a preparatory prosthesis and altering it through a series of mechanical revisions could be made more efficient if the effect of various component changes and modifications could be analyzed without having to physically implement them.

Most features of the Prosthetic Arm Design and Simulation (PADS) system have been implemented, and the utility of the system is ready to be evaluated in conjunction with clinical trials.

In operation, the prosthetist-user creates a software model of the subject and of the proposed

prosthetic arm (or arms). This is done by specifying a set of anatomical measurements for the human subject and a set of prosthetic components, along with their position and orientation. (For prosthetic components not included in the system, a utility enables the prosthetist to add the component to the system's library.) From this data, the PADS system generates a stylized four-view (front, right-side, left-side, and top) display of the human subject with a ball-and-stick representation of the prosthesis (balls representing joints; sticks representing limb segment lengths).

The system then calculates and displays the "functional workspace" within which the prosthetic prehensor can be positioned using only movements of the prosthetic joints and of the joints of the residual limb. The workspace can be viewed in its totality or for any subset of distal joints and in cross-section to reveal the inner geometry of the workspace (which is generally hidden by the exterior surface).

The PADS system also displays a "contact map" of all points on the body surface that can be touched by the prehensor. The combination of the functional workspace and the contact map can inform the prosthetist of the external and near-body reach available to the subject given the characteristics of the specified prosthesis. By varying components and their placement and orientation, the prosthetist-user can evaluate different configurations for their functional appropriateness without having to physically construct each configuration.

Recent Publications Resulting from This Research

Computer-based Component Selection and Assessment Tool for the Design of High-level Upper-limb Prostheses. Redding M, Masters Thesis, Northwestern University, Evanston, IL, 1991.

[13] Functional Biomechanical Characterization and Functional Design Specification: Upper-Extremity Prosthetics, Grasp Security

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—It is hypothesized that a reduction in the tendency for objects to slip when held in a prosthetic

prehensor will reduce the attention a user need give to the prehensor and thus increase the prehensor's

utility. Reducing this tendency for objects to slip will be investigated through the application of *materials to resist slip* and through *slip detection and automatic gripping*.

Progress/Preliminary Results—Materials to Resist Slip. All of the experiments to characterize the friction and deformation properties of elastomer surface materials have been completed. The study included neoprene (used to line Hosmer Dorrance split hooks), "rubber gripping pads" (used with the Otto Bock Greifer), polyvinylchloride (PVC) glove material (Otto Bock), and silicone glove material (Centri). No further results than those presented last year are available.

Slip Detection and Automatic Gripping. The development of a prototype slip detection and automatic grasping system has been completed. The system is based on a vibration transducer configured from a piezoelectric polymer polyvinylidene fluoride (PVDF). Signals arising from the transducer are

electronically processed to distinguish between vibrations caused by the slipping of a held object and extraneous vibrations, such as from the prehensor motor or from striking the prosthesis against a hard surface. By differentially amplifying the signals from two piezoelectric transducers made on the same substrate, common mode signals (remote, nonslip vibrations) can be reduced and differential signals (nearby, slip-related vibrations) can be enhanced.

The system has been installed on the NUVA Synergetic Prehensor, a high-performance prosthetic prehensor commercially available through Hosmer Dorrance Corporation. The characteristics of the Synergetic Prehensor are essential to the success of the automatic grasp response. Of the commercial electric-powered prehensors, the Synergetic Prehensor is the only one that can respond with an increase in force fast enough and of sufficient magnitude to stop the movement of a slipping object before it is dropped.

[14] Processing Strategies of Myoelectric Signals for Control of Upper Limb Prostheses

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Sponsor: Natural Sciences and Engineering Research Council of Canada

Purpose—Recent studies of the control of prostheses from a single myoelectric (ME) electrode have centered on various signal processing strategies. These strategies have been applied in an effort to extract more information from the ME signal. By focusing on the inherent characteristics of the ME signal, it is hoped that either an increased number of functions or finer proportional control could be achieved. This study attempts to summarize current strategies and then apply an adaptive processing strategy to ME signals.

Processing strategies of myoelectric signals have ranged from simple amplitude measurement to more sophisticated modeling techniques. These techniques include frequency spectrum analysis, statistical analysis, autoregressive models, and neural networks. All of these strategies are attempts to capture the intrinsic characteristics of the myoelectric signals in

order to more fully utilize them as control parameters. Each approach has advantages, but the simplest schemes have enjoyed the most clinical success to date. The more complex schemes still require development.

Methodology—A comparison of current processing techniques from a spectral information perspective will be made. From this, a processing technique will be outlined which might utilize the available information more efficiently. The technique will incorporate neural networks as an adaptive structure. Building on work done at the University of New Brunswick, the network will be trained on a number of sample ME signals and then will recognize patterns in new, previously unseen data. Implementation will then lead to clinical analysis of the chosen technique and its viability as a prosthetic controller.

[15] Evaluation of the Material Properties of Cosmetic Gloves for Upper Extremity Prosthetic Use

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Sponsor: University of Toronto; Hugh MacMillan Rehabilitation Centre

Purpose—The objective of this project was to investigate and evaluate the mechanical and chemical properties of cosmetic gloves made of polyvinyl chloride (PVC) for upper extremity prosthetic devices. The specific goals of the project were to: 1) determine the effect of ultraviolet (UV) light and humidity on the ultimate tensile strength and hardness of the material; 2) monitor any change in the plasticizer content of the material during natural and accelerated aging; and, 3) determine the stain resistance of the material.

Progress—Cosmetic gloves for prostheses, both custom fabricated and mass produced, have been primarily made from plasticized PVC. This material was selected because it is inexpensive, can be color-matched to a variety of skin tones, and is compatible with manufacturing processes which produce seamless parts.

Based on years of experience in using PVC gloves, however, issues such as low stain and tear resistance, toxicity, and temperature sensitivity have stimulated research into material replacements. At present, the characteristic modes of failure which result in glove replacement are not sufficiently known. Ultimate failures by fatigue, fracture and/or tearing are as much a characteristic of the glove design as they are of the material itself. Knowing the cause of the premature failure, among other specifications, will contribute to the development of the optimal product/material mix. As an important first step in identifying material replacements, investigations into the material properties of prosthetic

gloves are being conducted to establish levels of acceptable performance.

Methodology—Virgin material was collected from the cuffs of new, "as-received" gloves. These samples were cut in half to form two specimen groups. One sample represented the unaged material, and the other was placed through an accelerated aging process utilizing UV light (wavelength >290 nm), and moisture. Various failed or returned gloves constituted the third specimen group, referred to as gloves "aged-in-use."

A tensile test, Shore hardness test, and a chemical extraction of primary plasticizers are being performed on the three specimen groups. Statistical comparisons are being made between the unaged and the artificially aged material, and the unaged and the naturally aged material.

Preliminary Results—The effect of aging on the mechanical properties of the as-fabricated PVC are currently under investigation. Five unaged samples, three samples aged-in-use for 1 month, and three samples aged-in-use for 6 months have been tested. Based on the results of our preliminary investigation: 1) there appears to be no significant difference in the ultimate tensile strength between the unaged material and the material aged-in-use for 1 and 6 months; and, 2) the primary plasticizer content does not appear to vary significantly between the unaged material and the material aged-in-use for 1 and 6 months.

B. Upper Limb

2. Above-Elbow

[16] New Control Applications for Upper Limb Prostheses

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Sponsor: VA Rehabilitation Research and Development Service (Project #A306-2DA)

Purpose—Based on experiences with prostheses for persons with high-level amputations, this laboratory believes that body-powered or manually-positioned positive-locking components, with their comparative mechanical simplicity, general ruggedness, and low cost, have not been fully exploited. Mechanical arm prostheses can be configured for above-elbow and shoulder disarticulation fittings in which the body-actuated elbow/prehensor control cable can also be used to position positive-locking wrist components (for rotation and flexion). This configuration has many advantages. Perhaps most significant among these is that the cable control utilizes the otherwise intact musculoskeletal and sensory systems of the individual. Consequently, there is close coupling between the user and the prosthesis, presumably reducing the mental effort required in positioning the prosthesis. Once positioned, the joints are locked in place through some mechanical control.

We believe that the dependency on mechanical linkages to operate the locking mechanisms in these devices limits their effectiveness for the user and complicates the prosthetic fitting. To provide more efficient and versatile control of these components, a simple, modular electromechanical lock actuator is being developed which can be used in conjunction with existing cable-operated elbows and positive-locking wrist components. The principal advantage of the lock actuator is the replacement of the high forces needed to operate the mechanical controls with the considerably lower forces needed to operate an electrical switch controlling a motorized actuator. A second advantage is greater facility in placement and configuration of the switch control, over that possible with a cable or lever mechanically linked to the locking pin.

Progress/Preliminary Results—*Modular Electromechanical Lock Actuator.* A trial fitting of a prototype electromechanical actuator adapted to the locking mechanism of a cable-actuated elbow has been carried out in collaboration with the Orthotic/Prosthetic Clinical Service Department of the Rehabilitation Institute of Chicago. The elbow was part of a preparatory body-powered shoulder disarticulation prosthesis used by a person with quadrimembral amputations over a period of three-and-one-half months. The controller for the lock was operated by a momentary push switch mounted to the socket and actuated by the chin.

Reliability problems with the electronic controller and with the actuator itself have been corrected by relatively minor design changes. A redesigned actuator and controller were attached to a cable-actuated elbow and bench tested. The test was terminated after 300,000 successful cycles of locking and unlocking the elbow. The Rehabilitation Research and Development Evaluation Unit of the Department of Veterans Affairs is proceeding with a clinical evaluation.

Positive-Locking Shoulder. Toward the design of a locking shoulder, we are using a prototype computer-based prosthesis design system to investigate the hypothetical result of locking the shoulder joint (appropriate to a shoulder disarticulation amputation) at various flexion angles. The investigation showed that, with the locking shoulder joint, the work envelope in which the prehensor of the prosthesis can be positioned increased as did the body contact map (the area on the body which can be touched with the prehensor). The next step is to determine if a shoulder joint having a small number of locking positions (possibly only two or three)

could provide adequate functional advantage in comparison to a joint with a greater number of discrete positions or possibly a joint having infinite locking positions. A joint having a small number of locking positions may be simpler mechanically, which in turn may permit a smaller, lighter design.

Recent Publications Resulting from This Research

Four-Function Hybrid Arm Prosthesis Incorporating an Electric Wrist Rotator and Prototype Electric Prehensor. Uellendahl J, et al., in Proceedings of the 13th Annual RESNA Conference, Washington, DC, 167-168, 1990.
Physiological Control and Body-Powered, Multi-Joint, Locking Arm Prostheses (Abstract). Heckathorne CW, et al., Am Orthot Prosthet Assoc Almanac 39(1):117, 1990.

[17] Development of Advanced Body-Powered Prosthetic Arms

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Sponsor: VA Rehabilitation Research and Development Service (Project #A421-DA)

Purpose—The primary objective of this work is to design an advanced, body-powered artificial arm. The design criteria include: an adjustable elbow cable excursion to simplify fitting; a cable recovery system which will allow independent elbow and terminal device control—each with full cable actuation; a lightweight and strong structure with a front hinge for high excursion capabilities; and internal cabling using polymer cable materials for better cosmesis.

Progress/Preliminary Results—During the past year the work has been primarily in testing the prototype arm on amputees. Tests have been both in-laboratory and at-home wearing and operation of the arm. Many positive and some negative results have been collected. Complete analysis of the results will be presented in the final report of the project. The tests have covered all aspects of fitting, amputee training, and everyday use of the arm.

Use of Spectra 1000 cables for prosthesis use has been investigated. Both above- and below-elbow amputees have been fitted with the cabling systems on their present arms. Results indicate excellent acceptance by the amputees. The subjects have smoother motion and easier actuation, especially for fine manipulation with the Spectra cables, than with their steel cables. The life and strength of the

Spectra cable are comparable to steel cables with the possible exception of extremely heavy terminal device rubber band users. We are investigating heavier gauge Spectra cables to solve this problem.

An extremely important aspect in the choice of materials for the structure of the new arm is that of the impact strength of the arm. Impact strength tests were performed on various potential materials for the arm structure, including: glass fiber composite, carbon fiber composites (both filament wound and prepreg tape), Spectra fiber composite, and nylon reinforced injection molded. Cumulative damage to the structure, including cosmesis, delamination, fracturing, and complete failure of the materials, was examined. The results are being analyzed and will be presented in the final report.

Components of the mechanism have been cycle-tested for estimating their usable life. It is estimated that the replaceable parts will have a usable life of between 2 to 5 years, possibly more.

Future Plans/Implications—The results of the testing of the prototype current arm, cabling system, and structure will be used in the design of the next prototype arm. This arm will then be extensively evaluated at centers around the country. The results of this evaluation will be incorporated into the production arm.

[18] Extended Physiological Proprioception (EPP): An Electronic Cable-Actuated Position-Servo Controller for Upper-Limb Powered Prostheses

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Sponsor: *VA Rehabilitation Research and Development Service (Core Funds);
National Institute on Disability and Rehabilitation Research*

Purpose—Experience has shown that users of electric-powered multi-joint prostheses using velocity-control operation, such as with switch or myoelectric controllers, give considerable attention to the control of the prosthetic components, primarily through visual monitoring of the response of the component to the controlling action. Such systems having two or more powered components are generally arranged with the components operated sequentially so that the user need attend to only one component at a time. Efforts to provide coordinated control through multiple velocity-control sites have been, for the most part, clinically unsuccessful.

On the other hand, users of body-powered cable-actuated components generally appear to have better positioning control of their components and, in hybrid arrangements, are able to operate the body-powered components in a coordinated manner with velocity-controlled electric-powered components. The linkage of the body movement to the prosthetic component through the harness and control cable gives the user direct control over the position, velocity, and acceleration of the component and perception of that movement through the proprioception of the controlling physiological joints. D.C. Simpson (Edinburgh, Scotland) demonstrated empirically that linking body movements to externally-powered (pneumatic) components in a position-servo arrangement enabled children to control 4-degrees-of-freedom simultaneously in such coordinated activities as feeding. He called the approach extended physiological proprioception (EPP). We have demonstrated quantitatively, through 2-degree-of-freedom pursuit tracking experiments, the superior performance of cable-linked force-actuated position-servo control over velocity control.

We are now engaged in gaining clinical experience with this control system. We are also involved in attempts to improve the force transduction unit

that provides input to the force-actuated position-servo mechanism controlling the elbow.

Progress/Preliminary Results—Progress has been made along two fronts: 1) clinical experience with a one-degree-of-freedom controller; and, 2) alternate force transducer evaluation.

Clinical experience means having amputees fitted in a regular clinical facility (not a research unit) and having amputees use the system as their full-time prosthesis (i.e., in daily activities at home and work). Our first clinical efforts have been with the Orthotic/Prosthetic Clinical Service of the Rehabilitation Institute of Chicago. One unilateral above-elbow amputee has been using the control system effectively on a daily basis for more than 6 months to control an NYU-Hosmer electric elbow, in conjunction with a myoelectrically-controlled hand-like prehensor. Control of the electric elbow is similar to control of a body-powered elbow except that the excursion and force requirements to operate the elbow can be matched electronically to the needs of the user. Other clinical fittings are planned as subjects, for whom the system is thought to be the prescription of choice, become available.

In related clinical activities, we are collaborating with the Department of Clinical Neurophysiology at the Örebro Medical Center Hospital in Örebro, Sweden, to evaluate clinical fittings of one-degree-of-freedom EPP control systems similar to the ones developed here.

Progress has been made in force transducer unit development. We have endeavored to improve the force-sensing resistor (FSR) transducer unit being used. FSRs are nonlinear; a property that has been a negative factor in the performance of the total system, as designed here. We are investigating using two FSRs in the transducer unit in a kind of differential configuration to diminish some of the pronounced nonlinear influence. Preliminary results

have enabled us to improve performance of the unit.

New micropower strain gauge instrumentation in a transducer is also being evaluated as a substitute for the FSR-based units which are simpler, less complicated, and less costly than strain-gauge-based units. However, we feel we need to evaluate overall performance from some baseline and that a linear (strain gauge) unit would be a good one to use for comparison purposes.

Recent Publications Resulting from This Research

- A Micro-Power Strain Gauge Sampling Circuit for Use in Prosthetic Limbs. Gard S, Masters Thesis, Northwestern University, Evanston, IL, 1990.
- An E.P.P. Cable-Actuated Position Controller for Electric Elbow. Heckathorne CW, in Proceedings of the 17th Annual Meeting and Scientific Symposium of the American Academy of Orthotists and Prosthetists, San Diego, CA, 1991.
- A Micropower, Strain Gauge Sampling Circuit for Prosthetic Limb Applications. Gard S, Childress D, Heckathorne C, Med Biol Eng Comput (in press).

[19] Enhancement of the Variety Village 62 Elbow (VV62)

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Sponsor: *Variety Club of Ontario, Tent 28; Institute of Biomedical Engineering, University of Toronto*

Purpose—In 1988, the VASI VV62 elbow had been redesigned to enhance reliability and to increase speed. A custom 6-volt motor, designed to operate at twice the speed of the current production elbow, was ordered.

Unfortunately, this change lead to an unacceptable increase in the noise performance. The goal of this project was to identify the noise sources through acoustical analysis techniques. The specific goals were to: 1) use spectral analysis techniques to characterize the noise from the production model elbow, and to pinpoint the possible source(s); 2) utilize the same techniques to observe noise attenuation properties of changes made to the original production model; 3) monitor the noise spectra of both the production and the upgraded elbows while functioning within a prosthetic arm; and, 4) recommend possible design changes to the VV 62 elbow which would reduce its operational noise level.

Methodology—All acoustical testing of the elbow was performed inside a semi-anechoic chamber (an acoustically absorptive space), and all spectral data were collected and recorded with a Bruel & Kjaer Spectrum Analyzer and microphone. In the first phase of testing, the noise generated by the elbow alone was characterized, and possible sources found. To eliminate the possibility of any vibration being transmitted onto a testing stand, the elbow was suspended by thin nylon lines from a tripod during the recording of data.

Each set of meshing gears was removed individually to determine its contribution to the total noise spectrum. Shaft and motor speeds were also considered. For comparative purposes, the faster motor was tested in the elbow to quantify its effect on noise level. Other design changes included a new plastic bearing housing which was exchanged for the original aluminum bearing housing because of its possible noise-dampening properties.

Various changes were also made to the elbow's cover. Different types of plastic of various thicknesses were thermoformed into elbow covers in the hope of obtaining sound and vibration damping. High-density polyethylene, low-density polyethylene, and Kydex covers were compared to the original polycarbonate cover. By lining these covers with either a rubberized undercoating, a thick brown insulator, or a constrained layer damping sheet, further noise attenuation was attempted.

The last phase of the project was to obtain a more accurate representation of the noise spectrum generated by an elbow functioning within a prosthetic arm. Both the current production model and the upgraded model were tested within the prosthesis.

Results—The initial spectral analysis indicated that much of the noise can be attributed to the motor and to the ball bearing at the base of the worm. By operating the elbow within an above-elbow prosthesis, the noise level within the 1,000 to 5,000 Hertz

frequency range sharply increased, no matter which motor assembly, cover material, or dampening insulator was present.

A significant increase in noise attenuation was gained by replacing the original motor assembly with an upgraded assembly capable of operating at twice the speed of the original. When both motors were run at original operating speed, the upgraded motor assembly generated approximately 10 dB(A) less noise than the original design.

Even at twice the speed, the new motor assembly created noticeably less noise. Therefore, by replacing the original assembly, gains in speed and noise attenuation were achieved. Experimentation with various covers and sound-dampening insulators indicated that the present 1/16 inch thick

polycarbonate cover actually increases certain frequencies of noise.

By changing the cover material to 1/8 inch thick low-density polyethylene (LDP), appreciable noise attenuation was gained over most frequencies. Further attenuation was achieved by lining the inner surface of the LDP with a 0.015-inch layer of a constrained damping material. The new motor assembly and the LDP plus constrained layer insulator proved to provide the best noise attenuation overall. The upgraded elbow will incorporate the above recommendations.

Future Plans—Endurance testing on the upgraded model will be completed next, prior to its release for production.

B. Upper Limb

3. Below-Elbow

[20] Powered Prosthetic Fingers

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Sponsor: VA Rehabilitation Research and Development Service (Project #A306-2DA)

Purpose—The purpose of this project is to develop externally powered fingers (including thumb) that can be combined to create a functional, yet cosmetic, partial-hand prosthesis that will preserve the independent motion of the wrist. The secondary function of this project is to see if powered fingers and thumb can be used with persons who have wrist and below-elbow amputations. The fingers and thumb are to be the same size as those of an average adult. They are to have one articulation (metacarpophalangeal joint). The principle of synergy was adopted to boost overall performance. In a synergetic system there are at least two motors, one delivering high speed at low force and the other providing high force at low speed.

Progress—The system design uses three motors, all 10 mm in diameter, one each in the thumb, index finger, and middle finger. In order to achieve the optimum performance, the thumb provides the

speed and the index and middle fingers provide the force. The pinch force per finger is 8.5 lb_f which gives the hand a total gripping force of 17 lb_f.

The drive system for the thumb uses a bevel gear set attached to a reverse locking mechanism. This provides an angular velocity for the thumb in excess of 2 radians per second and an excursion of 3 inches at the tip. The thumb pivot is inclined at an angle of 45 degrees to the palmar surface. This maintains a cosmetic geometry for the thumb motion while providing a usable width of opening for the hand. The dynamic cosmesis and width of opening considerations for an inclined thumb are dictated by the synergetic design. This requires the thumb to provide all the width of opening while maintaining a dynamically cosmetic geometry.

Results/Future Plans—The first prototype system exceeded the proposed dynamic performance requirements, however, its size and weight precluded

any clinical applications. A second prototype of the fingers has been fabricated which is lighter, smaller, and incorporates design changes to improve perfor-

mance. It has not as yet been evaluated. The thumb will also be redesigned to improve its performance.

[21] Guidelines for the Type of Grip-Related Motions Required in Myoelectrically Controlled Hands

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Sponsor: *Natural Sciences and Engineering Council of Canada*

Purpose—This project will investigate the human hand during the process of grasping various objects in order to determine the most common types of grips (such as the key grip) and hand configurations (such as wrist angle) that are employed. Current prosthetic hand designs, both myoelectric and body-powered, will also be considered to determine the problems which exist with their flexibility in grasping certain objects (such as the conformation of the

fingers around a sphere or cylinder), as well as the visibility of the object just prior to grasping.

Methodology/Implications—The results of these investigations will be used to develop a list of guidelines for the range of grip-related motions that should be supplied by a prosthetic hand. These guidelines might then be used to improve current designs or develop new prototypes.

[22] Nevedac Electronic Hand Fabricated from Materials Available in India

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Sponsor: *Nevedac Prosthetic Centre*

Purpose—The purpose of this study was to develop a cost-effective electronic hand that could be fabricated from locally available materials.

Methodology—Electronic hands are of two types: the myoelectric control (electromyographic/EMG), and the switch control. In the myoelectric control system, the hand is operated through the electrodes which are fitted inside the socket of the upper limb prosthesis. These electrodes are highly sensitive, and a slight contact/signal activates it. Two sites are identified on the stump with the help of an EMG test meter. The electrodes fitted at the two sites govern two functions: one sends a signal to open the hand, and the other to close it. These electrodes are very expensive and are not available in India or in any of the other developing nations.

The switch control system is an alternative to myoelectric control. In this system, the micro-

switches used are activated by fitting them inside the socket where the muscle signal or stump contact is most prominent.

The Nevedac Electronic Hand works basically on the same principles as does the electronic hand in the advanced nations. The significant difference is that the Nevedac Electronic Hand has been fabricated from locally available parts with nothing imported from outside India. The main consideration has been to keep its cost within the reach of the average Indian patient.

The Nevedac hand is operated through the microswitch fitted inside the socket, where the muscle signal or stump contact is most prominent. This is located with the help of a signal tester, especially developed at the Nevedac Prosthetic Centre. The electric source is a 6-volt nickel cadmium battery fitted within the prosthesis. When the microswitch is activated, the current passes to the

motor through the circuit board. This results in the opening of all four fingers and the thumb. When the signal is released from the switch, the fingers are closed. The battery charges from a special charger in about 15 hours; the life of the battery is about 2 years.

Results/Implications—The Nevedac Electronic Hand has been fabricated from parts and raw materials that are available in India; therefore, its cost is very low (a few hundred dollars).

The weight of this motor-powered hand is about 500 grams, a little more than the mechanical hand being made in the Nevedac Prosthetic Centre. It is comparatively the same as motor-powered

hands made in the advanced nations. The gripping force is fairly good; it can hold a full glass of water very comfortably. The grip is enough to hold an object of over 1.25 kg. The fingers and palm are molded in ABS and covered with polyvinyl chloride (PVC) cosmetic gloves to give it a natural appearance, and to protect the mechanism from dust and moisture.

This electronic hand has been fitted successfully on some of our patients, including above-elbow and bilateral amputees. The response has been very encouraging. The greatest achievement has been that it is effectively functional, and comparatively low in price.

C. Lower Limb

1. General

[23] Videofluoroscopic Evaluation of Prosthetic Fitting and Amputee Stumps: A Pilot Study

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Purpose—The purpose of the study is to develop and apply a videofluoroscopic technique to evaluate dynamic stump-socket relationships during different phases of the gait cycle. This project has been undertaken since the clinical examination of stump complications arising from poor prosthetic fit can be subjective leading to inappropriate, expensive prosthetic modifications or replacement.

Progress—Three subjects have been studied while ambulating on a treadmill. Rubber lead markers were utilized to identify different parts of the inner socket. AP and lateral views of the stump and socket were taken using a Siemens Siregraph Fluorography Machine. Recordings were done using a Sony VO5800 Videorecorder. This allowed frame-by-frame analysis of stump motion inside the prosthesis. The following information could be obtained: 1) anteroposterior and mediolateral stump motion; 2) piston action; 3) rolling of soft tissues; 4) changes in stump volume; 5) air gaps at the distal

portion of the socket; 6) loss of normal stump socket relationships; and, 7) degree of knee flexion and extension.

Future Plans/Implications—Data from videofluoroscopy can be incorporated in the basic science field of amputee biomechanics and enhance our knowledge of normal stump-socket relationships during gait. Research along these lines may also generate new radiographic criteria for diagnosing various causes of stump pathology, poor prosthetic fit, and gait deviations in amputees. Videofluoroscopy has the potential to be a reliable tool for assessing the effectiveness of prosthetic readjustment or modification in the management of fitting problems. Long-term follow-up of patients fitted with their prosthesis with the assistance of videofluoroscopy can also be investigated in future studies.

Assuming that useful data are derived from this study, a potential application may be in the evaluation of newer prosthetic devices in terms of fitting

and patient comfort. Normative data derived from future studies can provide a basis for improving the design of new sockets.

We had already been monitoring patient satisfaction with the use of their prosthesis. This can be reinitiated in a future study by comparing overall patient satisfaction fitted with the aid of videofluoroscopy and a control group fitted in the traditional manner.

Videofluoroscopy can also be used to educate patients and their families, thereby improving patient compliance and self-care.

Recent Publications Resulting from This Research

Videofluoroscopic Evaluation of Prosthetic Fit and Amputation Stumps. (Abstract), Bocobo C, et al., Arch Phys Med Rehabil 71:806, 1990.

[24] Finite Element Methods for Below-Knee Socket Design

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Sponsor: VA Rehabilitation Research and Development Service (Project #A521-2DA)

Purpose—We have embarked on a series of projects with an aim to design socket shapes from fundamental principles of mechanics. Our approach is to model the limb/prosthesis interface through finite element analysis (FEA) methods. The aim is for these models to allow the computer to determine the socket shape needed to produce a specified pressure distribution in the socket. It will provide the capability not only to analyze existing sockets, but to design new prosthetic sockets that have not been previously feasible.

Progress—The use of both exact and individually scaled generic, geometric finite element models of below-knee (BK) residual limbs and sockets is being evaluated as a predictor of interface pressure. Clinical work involving measurement of the static load state and local interface pressures has been completed for three BK amputees wearing both unrectified and patellar tendon bearing (PTB) rectified sockets. This information, along with the results of *in vivo* indenter studies on the soft tissue of the residual limb of these amputees, has been used to complete the finite element models (define the load state) and to serve as experimental verification.

Additionally, the capability to create finite element models based on CAT scans directly from the digital scan tapes has been developed. This process takes only a few hours and greatly reduces the effort required to generate an accurate finite

element model. To date, a model of one BK amputee using this capability has been created.

Results—The assessment of the residual limb tissue properties indicates significant local stiffness variations (factor of 10), although intersubject stiffness variations were minimal. The range of modulus values for tissue we have measured is 13 to 90 kPa. These are small strain, linear approximations based upon a combined indenter and finite element studies. For all subjects, the popliteal area was the most compliant. The stiffest regions varied between the distal anterior tibia, medial femoral condyle, and fibular head.

The results of the finite element analyses and the clinical data indicate that: 1) the exact and scaled generic, geometric, finite element models are a fairly accurate predictor of normal interface stresses for the unrectified socket, with both experimental and theoretical local pressures ranging from 0 to 80 kPa; and, 2) the current modeling method of the prosthetic socket rectification results in large variations between theoretical and experimental pressures for the PTB rectified sockets, with the finite element model grossly overpredicting the normal interface stresses.

Implications—To investigate these discrepancies, efforts are currently underway to study alternative material property definitions for the soft tissue of the residual limb. Studies are also being conducted

to evaluate the adequacy of the generic, geometric approximation of residual limb geometry by preparing models which incorporate more accurate representations of: 1) the external surface of the residual

limb (based on digitization of an unrectified wrap cast); and, 2) the internal and external geometry of the residual limb (based on CAT scans).

[25] Dynamic Rectification and Alternative Fabrication for CAD/CAM of Prostheses

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Sponsor: VA Rehabilitation Research and Development Service (Project #A521-2DA)

Purpose—*Dynamic rectification* is a routine for computer-aided design (CAD) of prosthetic sockets which allows rectification patterns to be continually updated with each successful fitting. Present CAD programs provide a predetermined rectification map used as the first estimate of socket design and/or a platform for custom socket design without computer design assistance. We seek a computer interface which evaluates each successful CAD socket fitting, and builds a database of experience that can be drawn upon by the prosthetist, suggesting initial socket designs indicative of the individual technique of the prosthetist. Each successful fitting increases the quality of the design suggestions of the computer.

Alternative fabrication will integrate standard, industrial machine tools into computer-aided manufacture (CAM) of prosthetic sockets. Present prosthetics CAM systems are designed specifically for carving rectified limb models for molding sockets. These machines are costly and limited compared to standard, industrial, computer numerically controlled (CNC) machines. All functions of prosthetic carvers can be accomplished using an industrial CNC milling machine, and direct fabrication of prosthetic sockets can also be achieved.

Progress—*Dynamic Rectification*. The first implementation of dynamic rectification is a software routine which runs with the UCL ComputerShape software. Sockets may be classified according to age, stump shape, and prosthetist. Two rectification maps have been derived using 30 subjects who were successfully fitted using UCL ComputerShape. The user can add or remove a rectification from the database as desired. There is a regular averaging

scheme, and a weighted averaging scheme to emphasize certain rectification characteristics. The user can enter ComputerShape from the dynamic rectification software and use either the regular UCL rectification map or a dynamic rectification map.

The second phase accommodates axis alignment and socket normalization, not included in contemporary computer-aided socket design (CASD) software. Sockets requiring several iterations to reach successful fit may have improper alignment of the rectification map with the residual limb. We are investigating whether suitable normalization or rescaling of dimensions, or re-orientation of data might increase the success of fitting.

Alternative Fabrication. A 4-axis CNC milling machine was installed with a working volume of 30×16×16 inches and a rotational axis which can be mounted either horizontally or vertically. A computer program has been written to take a socket CAD datafile as input, and produce a CAM cutter location datafile that will drive the CNC mill. This routine, rather than producing a rectified socket model, will machine a socket directly from a block of material. A below-knee PTB socket with a uniform wall thickness of 7 mm was fabricated using blocks of poplar wood. The socket was fabricated in three sections to enable contouring of both the interior and exterior surfaces, and later bonded together.

Implications—Three benefits are perceived to result from dynamic rectification. An initial rectification is suggested by the computer which has a higher probability of producing a successful socket fit. The rectification map supplied by the computer includes the preferences and skill of the individual technique

of a prosthetist. Axis alignment automatically accounts for variations in data input and presentation.

Work to date suggests that special purpose machine tools are not necessary for CAM of prosthetic sockets and that direct fabrication of

sockets is possible with industrial CNC milling machines. A precision fit below-knee PTB socket was manufactured from wood as an illustration of the capabilities of CAM techniques.

[26] National Program for Automated Fabrication of Mobility Aids

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Sponsor: VA Rehabilitation Research and Development Service (Project #A521-DA)

Purpose—The Prosthetics Research Laboratory of the Northwestern University/VA Lakeside Medical Center (NU/VALMC) in Chicago—in collaboration with the Prosthetics Research Study (PRS) in Seattle, and the New York University/VA Manhattan Medical Center in New York City—has been involved in the National Program for Automated Fabrication of Mobility Aids (AFMA). The objective of this cooperative study was to conduct clinical and developmental testing of computer-aided design and computer-aided manufacturing (CAD/CAM) of sockets for below-knee (BK) prostheses. The equipment and techniques were primarily those currently available to prosthetists. Clinical fitting with a statistically representative sample of BK amputees were conducted to determine the efficacy of the present equipment and methods, and to uncover possibilities for refinement and improvement. Each center fitted approximately 40 amputees, for a total of approximately 120 amputees.

Results/Implications—Our center invited several practicing prosthetists to participate in the AFMA program. Several prosthetics laboratories from Illinois, Wisconsin, Ohio, and Tennessee responded positively. Thirty-seven qualified BK patients from our center and from participating prosthetics laboratories were part of the clinical study. Eight VA patients participated. The sockets were designed primarily through the equipment and techniques developed at the Bioengineering Centre of the University College London (UCL).

The final results of the clinical study are as

follows: 33 subjects have accepted the CAD/CAM sockets. Of these subjects, 10 subjects accepted the socket on one check socket fitting, 13 on two fittings, 8 on three fittings, and 2 on four or more fittings. Three subjects dropped out of the study, and fitting failed for one subject. Among the subjects who accepted the CAD/CAM sockets, the average number of fittings required for acceptance was 2.12 sockets per subject.

Aside from the UCL System, we also have the ShapeMaker from the Prosthetics Research Study, Seattle, WA, and the CANFIT-Plus from Vorum Research Corporation., Vancouver, BC. We have also evaluated these software systems.

Throughout the 2-year project, our laboratory has introduced and demonstrated to prosthetists from VA and private facilities this emerging CAD/CAM technology in prosthetics. To supplement our efforts in dissemination of CAD/CAM technology to prosthetists, our laboratory, in cooperation with the Northwestern University Prosthetic-Orthotic Center has offered a CAD/CAM demonstration course. Personnel from Shape Products Limited (formerly NUTEM, Ltd.), Advanced Rehabilitative Technologies, Inc. (ART), Vorum Research Corporation (formerly Shape Technologies, Inc.), and Prosthetics Research Study in Seattle were invited to demonstrate their computer-aided socket design products to participating prosthetists. The reaction of the participating prosthetists to this new technology was generally positive.

Our experiences with the system have been, in general, very positive. The CAD/CAM systems

being tested were found to be serviceable and adaptable to many BK residual limb shapes. It was noted that CAD/CAM frees up the prosthetist from many time-consuming tasks, and allows him to spend more time with the patient, improving the quality of the service provided to the patient. It was also found that several aspects of fitting BK amputees by CAD/CAM techniques were considerably easier than when conventional prosthetic techniques were used. With the CAD/CAM, it is easy to modify the shape, as well as to change the size of the socket with reasonably accurate predictions. The

CAD/CAM system not only makes accurately measured rectifications, it records them for future analysis. These records are useful for future reproduction of existing sockets, or for evaluation and analysis.

Many areas of the CAD/CAM systems were found capable of being improved and modified. In this ongoing VA-sponsored program, we are developing methods that we believe are practical and capable of advancing the application of CAD/CAM in prosthetics.

[27] Intraoperative Assessment of Amputation and Decubitus Flap Perfusion

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Sponsor: VA Rehabilitation Research and Development Service (Project #A463-RA)

Purpose—The surgical flap is a widely used and often effective closure following removal of necrotic and gangrenous tissue from a limb. This form of treatment permits salvage of limbs and tissues, thereby preserving more patient function and reducing requirements of extended rehabilitation. However, flaps used to cover an amputation site in the presence of peripheral vascular disease show an increased failure rate. In the spinal cord injury patient, flaps used to cover a pressure sore site show failures associated with suture separation and necrosis. Prediction of these failures before they occur would permit an alteration of surgical procedures with reduced morbidity and mortality. At the present time, the survival of the flap remains in question for days and sometimes months after surgery.

Methodology—Our hypothesis has been that quantitative measurements taken intraoperatively after the flap has been formed will assess flap physiologic function and predict flap survival. We have carried out intraoperative testing in volunteer patients in whom a surgical flap was developed as part of the normal surgical treatment. The testing determined

the presence or absence of perfusion based upon fluorescein flowmetry. In the laboratory animal studies (canine) using fluorometry, we evaluated changes in flow assessment with the measurement of proportional, rather than absolute, increases in dye concentration observed through the epidermis. Also examined was constant infusion fluorometry.

Results—Intraoperative test results were effective in prediction of tissue perfusion. This then provided an effective means of survival prediction intraoperatively as opposed to postoperative testing. Alteration in surgical procedures can be accomplished using intraoperative testing methods. The proportional index was independent of pigmentation. Constant infusion clearly delineated gradations in perfusion, correlating well with more time-consuming wash-out kinetic indices and accurately predicted viability.

Recent Publications Resulting from This Research

Monitoring Skin Fluorescence Delivery Independent of Skin Pigmentation. Silverman DG, et al., Surgery 108:48-55, 1990.

[28] Gait Analysis to Standardize Prosthetic Prescriptions: A Pilot Study

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Purpose—The goal of this research is to define standard methods of gait analysis using kinematic measures (i.e., time, distance, and joint angle parameters), and clinical assessments of performance to optimize lower extremity prosthetic prescriptions for geriatric veterans. Lower extremity prostheses are fabricated using physical measurements of the patient. The “goodness of fit” of prosthetic prescriptions is assessed by observational analysis of posture and gait in a clinic. Objective measurements of functional performance (in gait or balance) are not routinely used to ensure that the patient’s prosthesis has been optimally designed. If gait deviations are observed clinically, objective analysis of the patient’s gait is not used to guide the modification of the prosthesis.

This pilot study is designed to determine if standardized clinical assessment tools are sufficient and the most cost-effective means of ensuring functional gait in prosthetic patients. The study is also designed to determine if objective kinematic measurements are critical to ensuring good prosthetic gait—which measurements are essential, and how can they most easily be determined? To this end, we will answer these questions: 1) Can a standardized clinical assessment with observational analysis and a standardized patient self-assessment effectively identify gait abnormalities and problems with prosthetic fit in geriatric patients? 2) Is there a correlation in outcome measures from the standardized clinical assessment, the patient self-assessment, and the objective kinematic measures of gait in prosthetic patients? 3) Does two-dimensional (2-D) gait analysis in the clinic provide objective documentation of distance and time measures, which represent the “functionality” of gait? Do the measures of joint angle profiles provide a means to characterize the “smoothness” of gait?

Methodology—In this pilot study, we are studying geriatric veteran patients with prostheses for lower extremity amputations. We use two types of objec-

tive kinematic gait measurements of the prosthetic and sound limb (2-D and 3-D analysis), and two subjective functional assessments to characterize the performance of the patient in gait (the self-assessment questionnaire of the patient and clinical assessment from the physician and physical therapist). Standardized scoring methods are used for these data acquisition methods so that the measures of performance can be correlated. We will use these methods to develop a standard set of clinical tools to evaluate prosthetic fit through gait analysis. Comparison of performance measures will identify which tools are most effective for monitoring functional performance in prosthetic patients: these tools will be compared in terms of cost-effectiveness, for accuracy and precision of assessment, and as representations of the functional capacity of the patient.

Results—As part of the Quality Assurance Program in the Prosthetic Treatment Center, computerized gait analysis has been performed on 20 prosthetic patients when the Regional Prosthetics Clinic evaluated them for acceptance of a definitive prosthetic limb. Correlation of objective gait measures with the clinical assessment is in progress.

Future Plans/Implications—The results of this pilot study will provide data to design a broader study of objective gait analysis for the assessment of prosthetic alignment. We will develop a database of kinematic performance measures and their clinical correlates in geriatric prosthetic patients. We hypothesize that the use of 3-D gait analysis in prosthetic patients may be an important objective evaluation technique to monitor the effect of prosthetic modifications, and that 3-D gait analysis with ground reaction force measurements may be important in a select group of prosthetic patients in whom the professional staff have concerns about prosthetic fit and design. Three-dimensional gait analysis with kinetic data may play an important role in documenting the effect and/or need for prosthetic

revisions. Utility of these methods can only be assessed with a careful experimental analysis in which patients are studied before and after the prostheses are modified.

Recent Publications Resulting from This Research

Determining the Frequency Content of Gait Kinematic Measurements: Implications for Data Acquisition and Analysis.

Myklebust B, Myklebust J, Prieto T, in Proceedings of the 6th East Coast Clinical Gait Conference, East Lansing, MI, 1990.

Changes in Motor Function in the Elderly: Gait, Balance and Joint Compliance. Myklebust JB, et al., 13th Annual International Conference of the IEEE Engineering in Medicine and Biology Society, Orlando, FL, 1991.

Sensory-Motor Performance Changes in Healthy Aging Subjects. Myklebust B, et al., Soc Neurosci Abstr 17:1032, #410.8, 1991.

[29] Functional Biomechanical Characterization and Functional Design Specification: Lower-Extremity Prosthetics

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Purpose—The focus of this project area is on the development of a quantitative and theoretical understanding about prosthetics and orthotics. One of our goals is to form a “prosthetics/orthotics science” that can be used to guide thinking about the technical selection of prostheses and orthoses for people who need them, and one that will assist the development of improved prostheses and orthoses.

Instrumentation. A portion of effort is devoted to development, refinement, integration, and performance characterization of an instrumentation system for human mechanics measurement. Quantitative measurement is an essential component of empirical research and for formulating and testing hypotheses. The “quality of measurement” is related to the degree of fineness of quantitative observation and the potential power of conclusions.

Modeling. Biomechanical studies of the lower extremity focus on basic studies of non-amputees, studies of amputees with prostheses, studies of prosthetic components, and design and evaluation of prosthetic systems for lower-limb amputees. Non-amputees are studied to give a baseline understanding of activities such as walking and gait initiation, and to develop models that can be used to compare and evaluate the performance of amputees walking with prostheses. Studies of amputees and prosthetic systems provide insight into the relative efficiency of amputees using prostheses when compared with non-amputees, with theoretical ideals or

maxima, or with various prosthetic components. Development of prosthetic systems is directed at advancing prosthetics practice or fulfilling deficiencies in prosthetic alternatives. Included are three projects: 1) Pendular Characteristics of Human Walking; 2) Effect of Lower-Limb Stiffness on Human Gait; and, 3) Issues of Control in Hip-Disarticulation Walking.

Progress—Instrumentation. We are close to realizing a system which integrates two modified CODA-3 Instruments (six light planes). A statistical method is implemented (based on the method of maximum likelihood) which uses information from a redundant number (n) of light planes ($3 < n \leq \infty$) to form highest-certainty position estimates of marker locations. Also, a floor contact event (wireless) monitoring system has been developed. The system detects the event of single contacts touching a conductive floor without need for a tether connected to the subject.

Modeling. Walking, during the single support phase of gait, is akin to the behavior of an inverted pendulum. The torso moves forward over the stance leg much like an inverted pendulum. In fact, walking can be described as a series of inverted pendulum motions that are linked together by phases of double support. This similarity has led us to study the inverted pendulum and to compare its kinematics with characteristics of human gait.

One of our findings is that the simple pendulum model of walking can be used to predict the gait parameters of walking (e.g., swing time, stride length, cadence, and walking velocity) for children and adults. Another finding is that people of different size walk in a dynamically equivalent manner during self-selected free-paced walking, and that the gait parameters (e.g., velocity, time of swing, step duration, etc.), when properly normalized, are the same among individuals with various leg lengths. Our findings of "dynamic equivalence" are based on an inverted pendulum model of walking.

Also, we found that the duty factor (ratio of time one leg is in contact with the ground to the duration of one stride cycle) during self-selected free-paced walking is independent of the leg length and acceleration of gravity. People with different leg lengths will have the same duty factor when walking

at their self-selected free-paced speed. We are now investigating how this basic theory of walking can be advanced to assist the assessment of amputee gait, evaluation of prosthesis effectiveness, and in the design of improved prostheses.

Research on hip-disarticulation prosthesis control and limb stiffness is in progress.

Recent Publications Resulting from This Research

A Gait Analyzer Design Based on the Phase-Locked Techniques and a Simplified Spatial Conducting Path Model. Chong-Teh L, Masters thesis, Northwestern University, 1990.

On Aspects of (4-Dimensional) Dynamic Position Triangulation Using Multiple Light Planes and Retroreflectors. Van Vorhis R, PhD diss., Northwestern University, 1991.

Temporal Factors of Self-Selected Free-Paced Walking: Relationships to an Inverted Pendulum Model. Chan RB, Childress DS, in Modeling and Control Issues in Biomechanical Systems. ASME Winter Annual Meeting, Atlanta, GA, 1991.

C. Lower Limb

2. Above-Knee

[30] Computer-Aided Socket Design and Computer-Aided Manufacturing for Above-Knee Prosthetics

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Purpose—The objectives of this project are to: 1) develop an optical digitizer for remote, rapid, and accurate characterization of the spatial geometry and surface topography of the residual and contralateral limbs of lower-limb amputees for prosthetics computer-aided design/computer-aided manufacturing (CAD/CAM) system input; 2) adapt a four degree of freedom, computer numerically controlled (CNC), commercial milling machine for use in lower-limb prosthetics CAM; 3) develop quantitative design algorithms for quadrilateral (QUAD) and ischial containment (IC) prosthetic sockets; and, 4) implement and clinically test the QUAD and IC design algorithms developed in a computer-aided socket design and computer-aided

manufacturing (CASD/CAM) system for prostheses for above-knee (AK) amputees.

Methodology—To achieve these goals, the following protocol is planned. Specifications for an AK optical digitizer will be developed, a prototype procured, control and display software developed, and the resulting system clinically tested and refined. A commercial, four degree of freedom, CNC milling machine will be procured and modified, and CNC software will be written for lower-limb prosthetics CAM. Thirty AK amputees will be recruited as experimental subjects. A computerized database of their physiological, anatomical, biomechanical, and prosthetics characteristics will be compiled, ana-

lyzed, and used to develop quantitative CASD design algorithms for QUAD and IC sockets. CASD sockets and prostheses will be designed, manufactured, and fit on the experimental subjects. After usage for one month, the parameters of the CASD sockets will be measured and compiled in the project database. Statistical distributions of these parameters and their correlation with the physiological, anatomical, biomechanical, and prosthetics characteristics of the test subjects will be calculated. The results will be analyzed to identify trends in characteristics and categories of patients that are easily fit using the CASD algorithms, and those that are difficult and require considerable modification for successful fits. These results will be used to further refine and enhance the CASD algorithms.

Progress—Since the project began in April 1991, specifications for the optical digitizer have been developed and the requisite components for a prototype device ordered. Work on development of the digitizer control and display software has been initiated. Specifications and modification procedures for a CNC milling machine for prosthetics CAM are

also under development. The project database has been developed, and clinical trials of QUAD and IC CASD sockets on five AK amputees have begun.

Implications—Development of an optical digitizer for rapid, noncontact, measurement of the spatial geometry and surface topography, with automatic preservation of surface landmarks, of the residual and contralateral limbs of lower-limb amputees is vital for continued advancement of prosthetics CASD/CAM technologies. Development of such an optical digitizer will, in addition, provide prosthetists, physicians, and therapists with a quantitative means of assessing and recording anatomical and prosthetics characteristics of patients, and residual limb changes over time. Development of cost-effective procedures for modification of four degree of freedom, commercial CNC milling machines capable of carving the complex contours required in AK IC and other sockets, is also vital. In concert with these achievements, further development and refinement of socket design templates is essential to increase the socket quality and system productivity attained with prosthetics CASD/CAM systems.

[31] New Above-Knee Amputation Technique to Improve Gait and Energy Expenditure: A Pilot Study

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Sponsor: VA Rehabilitation Research and Development Service (Project #A89-2AP)

Purpose—This is a pilot study to investigate the effect of an adductor myodesis in an above-knee amputation, to hold the femur in its normal anatomical alignment as well as to maintain normal muscle tone.

Methodology/Progress—The surgery involves anchoring the intact adductor magnus muscle to the lateral side of the femur once the amputation has been performed. The quadriceps musculature as well as the remaining hamstrings are also anchored to the end of the femur. Once the wound has healed, the patient is then fitted with a standard above-knee prosthesis.

Three subjects who have had the above-mentioned surgical technique for their amputation have

been enrolled in the study. They are currently adjusting to the prosthesis. Once they are comfortable, they will be tested in the gait laboratory.

Their gait pattern will be analyzed and their energy expenditure measured. Three control subjects who have had a standard myoplastic above-knee amputation will be similarly assessed.

No definitive results are available at this time since difficulty was encountered in enrolling appropriate subjects.

Recent Publications Resulting from This Research

Transfemoral (Above-Knee) Amputation. Gottschalk F, In: Atlas of Limb Prosthetics. Park Ridge, IL: American Academy of Orthopaedic Surgeons (in press).

[32] Metabolic and Biomechanical Analysis of Above-Knee Amputee Prosthetic Componentry

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Sponsor: VA Rehabilitation Research and Development Service (Project #A620-RA)

Purpose—Above-knee (AK) amputation results in an increased metabolic energy expenditure during ambulation. The increased metabolic demand may limit ambulation endurance in young amputees and may preclude ambulation in the elderly amputee with limited cardiopulmonary reserve.

Recently, there have been two major components developed by prosthetic manufacturers to reduce the metabolic energy expenditure of ambulation: ultralight weight carbon graphite knee and shank components and energy-storing (dynamic elastic response) prosthetic feet. Theoretical analyses of human motion suggest that ultralight components may in fact result in an increased metabolic energy expenditure and that optimization of prosthetic mass and distribution of mass may depend on walking speed. The biomechanical and metabolic effects of energy-storing prosthetic feet in AK amputee gait has received little scientific study.

The purpose of this research is therefore to: 1) determine if ultralight prosthetic components influence the metabolic energy expenditure of ambulation, and if these influences are velocity-dependent; 2) determine the biomechanical correlates of changes in metabolic energy expenditure associated with ultralight components; 3) determine if energy-storing prosthetic feet influence the metabolic energy consumption of ambulation, and if the effects are walking-speed dependent; and, 4) determine the biomechanical correlates of the changes in metabolic expenditure associated with energy-storing prosthetic feet.

Progress/Methodology—A computer program is being developed to model the prosthesis as a damped pendulum with the ability to control and vary input variables including walking speed, hip torque and angular velocity, knee damping, prosthetic mass, and distribution of mass. With this model, we will calculate the mechanical work done at the hip under varying walking speeds, and foot/shank masses, and distributions of masses. The model will subsequently be subject to experimental verification and will lead

to the development of optimization criterion for AK amputee prosthetic characteristics.

Seven young, active above-knee amputees wearing ultralight weight carbon graphite components and seven nonamputees will be studied. The biomechanical data collection will include the acquisition of ground reaction forceplate and kinematic data with the subsequent calculation of muscle power outputs and energy flow across the joints. Data will be collected at the self-selected walking speed of the subject, and at three controlled velocities. Metabolic data collection will include the collection of expired gases in a Douglas bag during over-ground walking at the previously mentioned walking speeds. The expired gases will be analyzed and $\text{VO}_2/\text{kg}/\text{m}$ and $\text{VO}_2/\text{kg}/\text{min}$ will be calculated.

After collecting data with the ultralight weight prosthesis with conventional prosthetic feet, the protocol will be repeated after incrementing the shank masses and interchanging prosthetic feet.

At this time, we have nearly completed modification to the software and hardware used in the biomechanical analysis to optimize the resolution and accuracy of all aspects of data acquisition and analysis. These include: the development of correction factors to optimize center of pressure calculation from the ground reaction force plate, the modification of hardware and software to more accurately synchronize ground reaction force and kinematic data, and upgrading video hardware to super VHS format to enhance the resolution of the kinematic data.

A specialized "backpack" has been developed to allow the subject to transport the collection bag while ambulating over ground. In addition, a velocity controlled cane has been developed to determine the self-selected walking speed of the subjects, and to control the fixed walking speeds used in the experimental protocol. The metabolic data collection hardware has been tested and is now operational. Pilot data collected from nonamputee subjects correlates well with previously published data, confirming the validity of the experimental design.

[33] Clinical and Laboratory Study of Amputation Surgery and Rehabilitation

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Sponsor: VA Rehabilitation Research and Development Service (Project #A092-6RA)

Purpose—This project encompasses several studies concerning the surgical/medical treatment and prosthetic rehabilitation of amputees. The primary goal of the past year has been the completion of the VA/Seattle Lower Limb Prosthetic System for the above-knee (AK) amputee; the system for the below-knee (BK) amputee having been completed the previous year. This has required a concerted development effort on the VA/DAV/(Veterans Affairs/Disabled Veterans) Seattle Knee as well as other prosthetics components and techniques. Study of surgical technique and basic research into tissue viability have taken place at the VA Medical Center (VAMC), Seattle, as well as within our laboratory and at local teaching hospitals associated with the University of Washington. Development of Seattle ShapeMaker software has provided a platform for advancing the automated fabrication of mobility aids (AFMA). Collaborative AFMA studies are on-going with the Prosthetic Service at VAMC, Hines, IL and the Bioengineering Service at VAMC, New York, NY.

Progress—The VA/DAV/Seattle Knee is an entirely new design of a polycentric knee constructed of structural plastics. It features silicone fluidic control of swing phase and alignment stability of stance. The knee shares the design features of the other components of the VA/Seattle Limb: lightweight, flexibility, simplicity, and ease of manufacture. Four major prototype revisions have been tested using a universal testing machine, and in walking trials of volunteer amputee subjects. Three subjects are field-testing the latest revision.

Three versions of a new AK socket design have been created using the ShapeMaker AFMA software. The computerized modification scheme, "Template," is based on the anatomical considerations espoused by such designs as the NSNA, APO, and Narrow-ML. More than 20 amputee research subjects are field-testing the various designs.

An efficient technique has been developed for simple production of both flexible and rigid thermo-

plastic AK AFMA prostheses. The technique closely matches that developed previously for BK prostheses so that skills are transferable for making prostheses for both levels. A technique for AFMA manufacture of Symes level prostheses has also been perfected.

An "all terrain foot" (ATF) has been developed and tested for use as an alternative to conventional prosthetic feet. The ATF is made of high durometer rubber and its bottom is curved to match the motion of normal walking.

Education and dissemination of research has occurred through many courses, workshops, lectures, and publications by Prosthetic Research Study researchers. For example, an illustrated guide to basic prosthetics and prosthetic gait evaluation has been produced for training physical therapists and medical students at local hospitals.

Methodology—There are several varied and distinct methodologies for the studies carried out in this project. In general, projects concerning the Seattle Limb development were accomplished through the Clinical Engineering method, which relies on clinical observations and evaluations of successive prototype devices and techniques to refine design criteria. Ensuing iterations of designs based on those criteria are further evaluated by a team of amputee subjects, surgeons, engineers, and prosthetists.

Future Plans/Implications—Completion of the Seattle Limb and technology transfer of the revolutionary Seattle Knee are anticipated in the coming year.

Major development of the ShapeMaker AFMA software has been completed; however, a small effort will continue to provide task-specific extensions to the basic software platform.

We will also extend our research in the realm of tissue mechanics. We are especially interested in the manner in which skin changes and adapts under mechanical stress. These studies will build on basic research conducted in our laboratory regarding measuring and modeling the stresses within the dynamic prosthetic socket (reported separately).

C. Lower Limb

3. Below-Knee

[34] Efficiency of Dynamic Elastic Response Prosthetic Feet

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Sponsor: VA Rehabilitation Research and Development Service (Project #A517-RA)

Purpose—Recent development of durable flexible materials and their application to the prosthetic foot has provided a means of overcoming the rigidity of the solid ankle of the standard SACH foot while preserving durability. While below-knee (BK) amputees express a preference for the more dynamic feet over the standard SACH foot, subjects in our pilot work failed to demonstrate significant functional differences in the foot designs studied, which indicated that the discriminating parameters perceived had not been measured. Therefore, we have designed a more comprehensive research program based on the responses of the subjects in the pilot project and in work conducted by other laboratories.

Methodology—BK amputees are using five types of currently available prosthetic feet: four with a dynamic response design (Seattle, Flex Foot, Carbon Copy II, Quantum) and the SACH Foot.

On the amputated limb, two trials each of *free* and *fast* level walking; *ascending* and *descending stairs* and *ramp* are tested while the following data are collected: 1) stride characteristics, 2) dynamic EMG, and, 3) Vicon motion analysis. A single trial each of *free* and *fast* level walking is recorded to determine two force measurements: 1) the ground reaction forces in the medial-lateral, progressive, and vertical directions; and, 2) torque demand at the hip, knee, and ankle occurring during stance. On the sound limb, one trial each of *free* and *fast* level walking is recorded to determine the motion of that limb, ground reaction forces, and torque demands. Energy cost of free-walking on level ground is determined for each 5 minutes of a 20-minute walk.

Progress—Eight subjects have completed the project

(i.e., all five feet have been tested); five others are currently involved. As each subject completed the project, the response of the individual to the different foot types was examined. Each amputee appeared to respond uniquely to the changes in the prosthetic feet.

Preliminary Results—The ground reaction forces recorded demonstrated two significant differences. On the sound limb, the first vertical force peak (F1) was significantly lower for the Flex-foot (111% of body weight [BW]) than that induced by the other elastic feet (127-129% BW). There was a trend (which did not reach statistical significance with this sample size) for the SACH foot to induce the highest vertical (F1) force (137% BW). If these differences are substantiated by the larger study group, they hold particular significance for the dysvascular patients. Reduced loading of the sound limb would be a protective situation that could delay the threat of bilateral pathology.

The mechanism for this difference in contralateral loading was demonstrated by the timing of the posterior shear force on the prosthetic side (F5), though the magnitudes of this force did not differ significantly. For the Flex-foot, the posterior shear force was significantly delayed (54% of gait cycle [GC]) compared to 50% GC for the Quantum, Carbon Copy II and SACH. The Seattle foot also showed a delay in these peak forces (52% GC) which was statistically significant.

The gait velocity of the subjects fitted with the Flex-foot (84 m/min) was significantly faster than that permitted by the SACH foot (75.4 m/min). The intermediate walking speed (79 to 81 m/min) registered with the other feet was not a statistically significant difference. A larger sample size may

increase the pertinence of these differences. One finding was the significantly longer stance time on the sound limb compared to the amputated side (65.3% GC versus 62.9% GC).

The quantitated EMG data collected during ambulation on stairs and a ramp has been analyzed for the first 10 subjects tested with the Seattle foot. The EMG demonstrated intense and prolonged action by the hip extensors and quadriceps. This confirms the need to emphasize strengthening in the amputee's rehabilitation program as well as gait training and prosthetic management.

During all ramp and stair activities, the amputees displayed a slower velocity, reduced single stance time, and prolonged double support periods compared to normal values. These differences in stride characteristics imply slightly reduced prosthetic limb stability.

Future Plans—The individual variability among subjects has necessitated analysis of the separate records as well as compilation of the data for mean patterns and group significance. Preliminary assessment of these individual results suggests that the subjects may have to be subclassified according to their general physical status as well as type of amputation. This will be explored further as results from more subjects become available. As the functional patterns and differences become clearer, the data will be analyzed for their clinical pertinence and for areas where further study may be indicated.

Recent Publications Resulting from This Research

Below-Knee Amputee Gait with Dynamic Elastic Response Prosthetic Feet: A Pilot Study. Torburn L, et al., *J Rehabil Res Dev* 27(4):369-384, 1990.

[35] Gait Initiation in Below-Knee Amputees: Analysis of Safe Function

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Sponsor: VA Rehabilitation Research and Development Service (Project #A613-RA)

Purpose—The objective of this project is to investigate the transient movement phenomena associated with gait initiation in below-knee (BK) amputees. This study will record how variation in prosthetic alignment, speed of movement, and choice of initial swing limb (intact or prosthetic) affect the safety and efficiency of gait initiation.

The neuromuscular coordination necessary for balance maintenance and postural control is compromised in the amputee. Feedback channels, including calf muscle spindle activity and ankle joint proprioceptive signals, are lost. Since functional (daily living) activities require frequent transitions from stance to ambulation, amputees need to develop skills to safely negotiate the involved weight transfer and postural imbalances. This study will investigate the strategies the BK amputee uses to compensate for musculoskeletal asymmetry, and will provide insight into the potential for gait training or prosthetic mechanical design to improve patient function.

Methodology—The ground reaction forces, center of pressure location, and lower-limb electromyographic (EMG) activity will be monitored in three groups of subjects: 1) 20 age- and sex-matched normal controls; 2) 20 unilateral BK amputees with good ambulatory skills who will use an adjustable prosthesis for testing sessions; and, 3) 20 BK amputees wearing conventional prostheses. The subjects will stand on force platforms and begin walking at slow, normal, and fast speeds with their intact and prosthetic legs. Subjects with adjustable prostheses will have adjustments systematically made to their prosthetic limb (socket tilts and shifts, foot eversion/inversion and plantar/dorsiflexion, changes in prosthesis length), and will then repeat the gait initiation trials. Results of the normal and amputee populations will be compared, and changes in gait initiation behavior with change in prosthesis alignment will be noted. Specifically, magnitude and direction of center of pressure excursion, magnitude and timing of peak vertical and shear ground reaction forces, and sequence of electromyographic activity including periods of antagonistic co-contraction will be recorded and used to evaluate the symmetry, safety, and efficiency of the movement preparation.

Progress—The instrumentation necessary to perform this study has been acquired and installed. The force plates and EMG equipment have been interfaced to a computer and configured to enable high speed

multichannel data acquisition. Verification of the system is underway. Volunteers for the study have been recruited and adjustable prostheses for two of these subjects have been constructed.

[36] The Diabetic Foot with Partial Amputation

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Sponsor: VA Rehabilitation Research and Development Service (Project #A573-RA)

Purpose—The purpose of this study is to conduct a retrospective biomechanical evaluation of diabetic veterans with successful partial amputations of the foot. The results of the study should lead to a better understanding of the partially amputated foot and a better definition of criteria that should be used for management during rehabilitation. Favorable results could be extremely important in convincing surgeons that a partial amputation is a viable procedure, thus resulting in the saving of many limbs that would otherwise have been amputated.

Methodology—Four groups are being formed according to the following levels of amputation: 1) hallux and first ray resection; 2) other digital and ray resections; 3) transmetatarsal amputations; and, 4) short transmetatarsal amputations, Lisfranc's and Chopart's procedures. Ten patients in each group will be studied. The shape of the partial foot will be measured. Additionally, traditional range of motion, strength, and deformity measurements will be taken, together with a battery of gait analysis parameters, including pressure distribution and kinematic measurement. Results will be compared

with the "classical" opinions concerning the partial foot and a number of hypotheses with respect to deformity and function will be tested. This study will also examine the intact foot to assess the presence of a number of putative risk factors.

A complete medical history, and measurement of sensation, strength, and range of motion of the lower extremities are collected together with photographs, a bivalve cast of the amputated foot, and weight-bearing anterior, posterior, and lateral X-rays. Footprints, pressure distribution, and simultaneous kinematic analysis comprise the dynamic data collection protocol.

Preliminary Results—Kinematic protocols to obtain the 3-D locations of markers on the foot and a rigid body model of the foot have been finalized. We are continuing our search to identify sufficient numbers for a statistically relevant subject pool: only about one-third of the number necessary have been identified to date. Searches continue at facilities within reasonable traveling distance while hardware and software development is being finalized.

[37] Normal and Shear Stresses on a Residual Limb in a Prosthetic Socket

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Sponsor: VA Rehabilitation Research and Development Service (Project #A092-6RA)

Purpose—The purpose of this research is to investigate mechanical loading on a residual limb in a prosthetic socket during ambulation. Results will

provide insight into how prosthetic design parameters affect interface normal stress and shear stress loading patterns, information applicable to pros-

thetic design and fitting and residual limb tissue mechanics.

Methodology—Experimental and analytical methodologies are used. Custom-designed transducers to measure both normal stresses and shear stresses at the residual limb/prosthetic socket interface are developed and they are used in clinical studies on unilateral below-knee amputee subjects. This is a significant advance in below-knee prosthetics since biaxial shear measurements have not been previously achieved. Forces and moments in the prosthetic shank are measured simultaneously. Prosthetic design parameters of interest are changed in different trials and the effects on interface stresses and shank forces and moments are analyzed.

An analytical model is developed for each subject under clinical investigation to calculate interface stresses during walking, based on mechanical characteristics of the residual limb and prosthesis. Interface stress results are then compared with the stress data collected in clinical walking studies to evaluate the quality of each model. This methodology is original in that modeling of dynamic interface stresses has not been previously attempted. When a well-functioning modeling methodology has been developed, models can be used to evaluate stress sensitivity to prosthetic design parameters controlled by a prosthetist.

Progress—A 16-channel instrumentation system to measure interface stresses in three orthogonal directions simultaneously with forces and moments in the prosthetic shank has been fabricated. Evaluation studies showed that transducer instrumentation errors were less than 4.2% and 0.9% for normal and shear directions respectively. Other errors including non-uniform loading, sensor surface area limitations, air leakage, crosstalk, and dynamic response have been well-evaluated.

In a clinical session, approximately 72 steps are collected at each of three socket/shank alignment settings. Each session lasts approximately 30 minutes.

A functional model has been developed for one subject. Using the ANSYS finite element code, the model has approximately 800 elements and is run on a MicroVax workstation.

Results—From data collected in nine clinical sessions conducted on three subjects, repeated characteristics in interface stress waveforms from different steps and from different subjects have been identified. Their relationships to events in prosthetic shank force and moment waveforms have provided insight into physical meaning and clinical relevance of those characteristics.

Angular alignment changes made to a prosthesis during a clinical data collection session did not significantly alter peak interface stress magnitudes within a step. However, alignment changes did modify waveform shapes.

Results from the first analytical model show that the model performs well at proximal sites. However, it does not perform as well at distal sites, probably because loss of contact between the residual limb and socket was not allowed. Further modeling efforts will use interface elements to overcome this limitation.

Future Plans/Implications—Future research will concentrate on skin adaptation to interface stresses measured in this project. Understanding biological assembly and reorganization processes involved in adaptation and developing methods to facilitate development of desired biostructures appropriate for interface loading will be the thrust of the work. Gaining insight into adaptation sensitivity to clinically-relevant mechanical parameters such as loading frequency, loading history, and tensile and biaxial stress configurations will also be pursued. The overall goal is to apply this clinically to 'design' skin for load-bearing function.

Recent Publications Resulting from This Research

An Angular Alignment Measurement Device for Prosthetic Fitting. Sanders JE, et al., *Prosthet Orthot Int* 14:143-144, 1990.

Ambulation with a Prosthetic Limb: Mechanical Stresses in Amputated Limb Tissues. Sanders JE, PhD Diss., University of Washington, 1991.

Stresses on a Residual Limb Inside a Prosthetic Socket During Walking. Sanders JE, Daly CH, Boone DA, American Orthotic and Prosthetic Association National Assembly, Anaheim, CA (accepted for publication).

[38] Knee Extension-Flexion Sensory Biofeedback for Above-Knee Amputees

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Sponsor: Moss Rehabilitation Hospital

Purpose—One of the problems facing above-knee amputees is the absence of sensory feedback pertaining to knee flexion/extension with a prosthesis in which the knee is allowed to move. Although the experienced amputee has developed strategies to assure that the knee is locked before weightbearing, the new amputee often has difficulty assuring that the knee is fully extended before transferring weight onto the prosthesis. A collapsing prosthesis does little to instill confidence in the new amputee and promotes undesirable gait deviations.

Currently under investigation is a device developed in our laboratory intended to provide the above-knee amputee with some feedback to assure

that the knee unit in the prosthesis is fully extended and ready for weight acceptance in stance.

Progress/Methodology—A potentiometer is placed laterally over the knee joint of the prosthesis and fixed to the leg. The potentiometer output is fed into a modified electrical stimulation unit (Medtronic NMA Surface Stimulator #1385b) which provides surface electrical stimulation to the patient when the desired knee angle is obtained. The stimulation intensity is inversely proportional; intensity decreases as the desired angle is approached. The device appears to work as specified and the clinical application trials are to follow.

[39] Flexible Keel Foot Prosthesis Allowing Mediolateral Control

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Sponsor: National Health Research and Development Programme; Natural Sciences and Engineering Research Council of Canada

Purpose/Methodology—Many flexible keel foot prostheses have a strong geometric symmetry about the long axis of the foot. This work presents a new concept based on the capacity of the flexible keel to allow more mediolateral function than previously available while storing and releasing energy in the sagittal, transverse, and frontal planes. The principal ones are a medially concave shape at the heel, followed by lateromedial change of direction from the heel to a more central foot position, making a hump in the mid-foot section to end with a curved toe extremity. The first and last curves contribute to an increased mediolateral propulsion during weight transfer and push-off.

Results—Results for a 16-year-old below-knee (BK) amputee consecutively fitted with the SEATTLE FOOT and the new design, the SPACE FOOT, illustrate the potential of this third-generation flexi-

ble keel foot prosthesis. Foot switch, video, and forceplate measurements were collected. With the SPACE FOOT, there was a 14% improvement in the average natural walking speed resulting from a 5% cadence and 9% stride length increases. More markedly was a reduction in the initial and terminal double support period asymmetry due to a 75% increase in the relative duration of the initial double period of the affected limb. These phasic gait improvements are thought to be directly linked with a better mediolateral propulsion provided by the SPACE FOOT. During push-off, increases of 36% in the anterior forces occur. During weight transfer from the sound to the prosthetic side, the maximum medial braking force is increased by 17%. This results in a faster natural walking speed manifested by a relatively longer double support period, greater mediolateral propulsion, better weight transfer capabilities, and improved push-off force. The overall

effect is seen in a longer stride length and increased cadence reaching a walking speed that is closer to normal.

Patents

Flexible Keel Foot Prosthesis (Allowing Mediolateral Control).
American patent application filed for May, 1991.

Recent Publications Resulting from This Research

A Flexible Keel Prosthesis Allowing for Both Sagittal and Medio-Lateral Propulsion. Allard P, et al., *Orthopadie-Technik* (in press).
Running Gait Impulse Asymmetry in Below-Knee Amputees. Prince F, et al., *Prosthet Orthot Int* (in press).

[40] Study of Abnormal Stresses on the Contralateral Foot of Below-Knee Amputees in Leprosy

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Sponsor: Poona District Leprosy Committee

Purpose—The human bipedal locomotion is characterized by its symmetry. This is possible due to the intricate combination of the neuromuscular and skeletal systems working in harmony to produce a smooth gait. The available literature suggests that amputees may demonstrate an asymmetrical gait pattern. Further studies done by other authors in another group suggest that forces occurring during amputee gait may be unequally distributed between the contralateral leg and the prosthetic leg. Moreover, lack of confidence in the limb, discomfort in the stump, and poor balance might lead to reduced weightbearing on the prosthetic side. Because the weight of the prosthesis is lower than the weight of the amputated limb, some reduction in weight-bearing is also expected on the prosthetic side.

Under such circumstances, the stresses and strains occurring in a neuropathic leprotic foot during the gait on the contralateral foot of unilateral amputees (below-knee) may become exaggerated. These stresses can get magnified if there is associated muscular paralysis. In another group of patients (with intact limb lengths), in a separate study conducted at our institution, it has already been proved that increased and abnormal shearing forces occurring during the heel-toe pattern are the causative factors both in occurrence and progression of neuropathic changes. Therefore, the purpose of this research was to study the long-term influence of these abnormal stresses, mainly in the form of plantar ulceration and tarsal disintegration (TD), occurring in the nonamputated neuropathic foot of unilateral below-knee amputees.

Progress—Thirty below-knee amputees (who underwent amputation in the last 10-20 years either for squamous cell carcinoma or for advanced changes of TD with unstable ankle) who reported to the Dr. Bandorawalla Leprosy Hospital, Kondhawa, Pune, India, either for repairs to prostheses, or with stump problems, or plantar ulceration in the nonamputated foot, were enrolled in the study. Personal histories and detailed clinical and radiological examination of the nonamputated leg was done.

Preliminary Results—Fresh TD was observed in two cases: both developed neuropathic variety of TD. Amputations were performed on the other foot due to advanced septic TD changes. Seven cases were found to have developed fresh ulcers and six had recurrence at the previous sites.

Future Plans—Further research work includes the influence and correlation of the following factors on the contralateral neuropathic foot: 1) occurrence of fresh ulcers; 2) recurrence of old ulcers (factors 1 and 2 to be compared with the duration of ulcers from the time of amputation); 3) presence of short foot (type of gait adopted); 4) presence of foot drop; 5) type of footwear or special appliance used; 6) sensory status; 7) occurrence of TD (history of trauma); 8) recurrence of old TD (factors 7 and 8 to be compared with the duration of TD from the time of amputation); 9) use of prosthesis (average time during the day); and, 10) occupation of the patient.

[41] Sports Leg

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Sponsor: *Rehabilitation Engineering Centre*

Purpose—A below-knee sports leg is being developed which uses the strength, lightness, and flexibility of carbon fiber composite. This will store and return energy to the user quite effectively and will provide increased durability over existing modular limbs for activities such as golf.

Progress—The main member has been manufactured by a local aerospace company and is currently being fitted to a patient for further development.

II. Biomechanics

A. Bone and Joint Studies

[42] Patient-Specific Finite Element Modeling of Bone from CT Scan Data

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Sponsor: VA Rehabilitation Research and Development Service (Project #A371-2RA)

Purpose—The objective of this project is to develop, verify, and document accurate methods for deriving the mechanical properties of inhomogeneous bone from CT scan data for the definition of three-dimensional (3-D), patient-specific finite element (FE) models. Several methods of evaluating the mechanical properties of the finite elements will be examined, including a new method that treats each element of inhomogeneous bone as a composite material. The accuracy of the methods will be determined by comparing the predictions of FE models with the results of mechanical tests of bone specimens.

Methodology—CT scans of human proximal tibiae, proximal femora, and distal femora will be obtained. Cubic specimens of trabecular bone will be cut from the intact bones, and specimen stiffness will be measured in three orthogonal directions. Correlations between the elastic modulus and CT scan density of the specimens will be derived and compared with existing relations. Tests will first be performed for relatively homogeneous specimens; density-modulus relations for these specimens will form the basis for development of the new method of deriving the material properties of bone.

To develop this new method, FE models of each test specimen will be generated from CT scan data, and a predicted stiffness in each direction of mechanical testing will be computed. Predicted stiffness will be compared with measured stiffness to establish accuracy of the FE models. Initially, each

element in an FE model will correspond to one CT scan pixel so that the variation in material properties within the specimen will be modeled with the same high resolution as the CT scan. Once accuracy of these FE models is established, the new method of computing the orthotropic properties of the finite elements will be developed. This method will use the theory of composite materials to treat each element as a composite of subelements, with each subelement corresponding to a pixel of CT scan data.

Progress—Human tibiae and femora have been obtained. CT scanning and mechanical testing of specimens from proximal tibiae is in progress. A method of quantitatively assessing the 3-D homogeneity/inhomogeneity of the trabecular bone has been developed which uses quantitative computed tomography of the intact bone. It is being used to assess the homogeneity of the trabecular bone specimens. Software for automatically generating FE models of bone specimens from CT scan data also has been developed. The various methods of computing the mechanical properties of bone will be incorporated into this program. Initial FE models of the specimens have been analyzed.

Results/Implications—Preliminary results of mechanical testing indicate that the average modulus of a specimen is correlated with the CT scan-derived density ($R^2=0.90$). Correlations for the moduli in the individual test directions are not as strong.

Studies of homogeneity revealed that nearly all of the test specimens were too inhomogeneous to allow assumptions of homogeneity to be valid. This indicates that correlations between average specimen density and modulus, which imply homogeneity of the test specimens, contain a large source of error.

The FE models show great variations in modulus within the specimens, in agreement with our homogeneity measurements. In addition, the stiffness values predicted by the FE models depend on direction, and are not simply proportional to the average CT scan densities. This is consistent with our belief that inhomogeneity of the bone specimens

affects the mechanical behavior. The FE models of the specimens can account for inhomogeneity, and therefore may improve mechanical property predictions.

Recent Publications Resulting from This Research

Automated Three-Dimensional Finite Element Modeling of Bone: A New Method. Keyak JH, et al., J Biomed Eng 12(5):389-397, 1990.

Strain Gauge Verification of an Automated Method of Finite Element Modeling of Bone from CT Scan Data. Keyak JH, et al., in Transactions of the Orthopedic Research Society (in press).

[43] Correlation of Streaming Potentials with Stages of Bone Repair/Remodeling

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Sponsor: VA Rehabilitation Research and Development Service (Project #A160-3RA)

Purpose—The processes of bone repair and remodeling are central to the welfare of patients after fractures and/or bone surgery, as well as in conditions ranging from spinal cord injury to osteoporosis, which affect the homeostasis of bone. While bone repair/remodeling is thought to be influenced by mechanical forces, the transducing signal that controls bone cell activity remains undefined. Circumstantial evidence points to mechanically induced fluid flow in bone with concomitant production of streaming potentials (SP), also known as stress-generated potentials, as a possible control mechanism. *In vivo* studies of SPs in normal bone have been few and nothing is known of their occurrence or characteristics during reparative or resorptive processes. Although various mechanical and/or electrical systems are being developed or are in clinical use in attempts to affect bone healing as well as osteoporosis, the relationship of SPs to these treatment modalities remains unclear. This project aims to define how SPs relate to specific stages and types of bone healing and remodeling, as a step toward determining their clinical significance.

Progress—The investigators previously developed a model for studying the magnitude and frequency dependence of SPs in living canine tibia using a

regime of bending deformation (0.1-40 Hz) applied by a specially designed servohydraulic loading system. The SPs are measured by an improved design of Ag AgCl electrodes suitable for *in vivo* measurements during free walking, and during controlled tibia loading by the servohydraulic system under anesthesia. These techniques are in use in our other current work that seeks to study the effects of circulatory, biochemical, and structural factors on SPs in normal intact bone.

During the first year of this project, certain modifications of our electrode and systems were made to adapt the system to SP measurements on drill holes and osteotomies. During the remainder of the first year and part of the second year, measurements were completed on our drill hole model. During the remainder of the second year, our osteotomy model was tested and, after certain modifications, work was initiated on 6- and 12-week tibial osteotomies. During the second year, experimental work was completed on seven of nine planned osteotomies leaving the project essentially on schedule. Data analysis is still in progress.

Methodology—Using the techniques described, SPs are measured *in vivo* and *in vitro* on three different models in canine tibia.

- 1) **Drill Hole Model:** SP measurements during servohydraulic loading at 2, 4, and 12 weeks during the healing process of 4 mm drill holes in canine tibia. The onset and nature of SP produced by bone as it fills the drill holes is documented and correlated with histological structure and porosity of the new bone.
- 2) **Osteotomy Model:** SP measurements on bone and callus during programmed servohydraulic loading at 6 and 12 weeks during healing of 8 mm gap osteotomy stabilized with an external fixator. SPs are correlated with callus stiffness and histology. Disturbances of the normal electrical patterns of SP during bone regeneration that may be caused by placement of metallic fixation devices, or by artificial stimulation by microampere currents also are being studied.
- 3) **Disuse Atrophy Model (scheduled for Year 3):** After 6-week immobilization of one hindlimb, SP will be measured as a function of the increased porosity of cortical bone in the immobilized tibia, in comparison with the contralateral limb exposed to continued weightbearing.

Results—Preliminary indications suggest that SP from healing bone (3-month-old drill holes) may be larger than SP from cortical bone. Whereas SP at early healing stages may be smaller, although streaming currents may be higher. SPs also have been shown to be present at 6 and 12 weeks at the healing site of 8 mm gap osteotomies with larger streaming potentials present at the osteotomy site when it is not completely bridged by bone. The significance of these findings awaits further data analysis.

[44] Surgery Simulation: Computer Models to Study Reconstructive Surgeries

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Sponsor: VA Rehabilitation Research and Development Service (Project #B554-RA)

Purpose—When human limbs are impaired due to disease or trauma, function can sometimes be recovered with surgical reconstruction. Such surgical reconstructions, however, often compromise the capacity of muscles to generate force and moment about joints. Lack of sufficient muscle strength or moment arm may leave the patient with a nonfunctional limb. At present, surgeons have no quantitative tools to preoperatively evaluate the effect of a planned surgical procedure on muscle function. As a result, the success of many reconstructive surgeries is marginal, and the innovation of new procedures is limited.

A more effective way to design reconstructive surgeries is to use computer models of the musculoskeletal system to understand the biomechanical consequences of surgical procedures. The objective of this study is to develop computer models to study the effects of reconstructive surgeries on the complex behavior of the musculoskeletal system. We hypothesize that the body can be adequately represented by computer models, and

that the use of such models will significantly improve the surgeon's ability to plan surgeries by providing information about the effects of a planned surgical intervention on muscle-tendon moments. It is expected that improved understanding of a surgical intervention will lead to more effective surgeries, and therefore will improve the functional result.

Preliminary Results—To date, the previous planar model of the human lower extremity has been extended to 3-dimensions. Also, the interactive model has been implemented on a graphics workstation. Computer graphics are used to visualize the complex interactions among components of the musculoskeletal system, and as an important communication tool for interacting with surgeons. The model was used to evaluate the effect of tendon lengthening surgeries by studying the sensitivity of isometric muscle force to change in tendon length. It was found that muscles with short fiber lengths (e.g., soleus, gastrocnemius, tibialis posterior) are

most sensitive to change in tendon length. The model was also used to evaluate specific lower-extremity tendon transfer procedures.

Recent Publications Resulting from This Research

Biomechanical Analysis of the Chiari Pelvic Osteotomy: Preserving Hip Abductor Strength. Delp SL, et al., Clin Orthop 254:189-198, 1990.

An Interactive Graphics-Based Model of the Lower Extremity to Study Orthopedic Surgical Procedures. Delp SL, et al., IEEE Trans Biomed Eng 37(8):757-767, 1990.

A Musculoskeletal Model of the Human Lower Extremity: The Effect of Muscle, Tendon, and Moment Arm on the Moment-Angle Relationship of Musculotendon Actuators at the Hip, Knee, and Ankle. Hoy MG, Zajac FE, Gordon ME, J Biomech 23:157-169, 1990.

[45] Contact Pressure in the Hindfoot

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Sponsor: VA Rehabilitation Research and Development Service (Project #A553-RA)

Purpose—This study aims to contribute to the understanding of the biomechanics of the subtalar joint by studying contact areas and pressures. The subtalar joint is involved in all hindfoot functions including dorsiflexion, plantarflexion, inversion, eversion, and internal and external rotation. It can be affected by angular deformities, fractures, arthritis, malunions, and imbalance in muscle forces secondary to neurologic disorders. In Phase I of this project, we studied contact characteristics of the subtalar joint under axial loading through tibia only, and through tibia and fibula. In Phase II, the effect of talar neck displacement of several magnitudes and directions after fracture was studied.

Progress—The loading system developed in Phase I was applied to the study of simulated talar neck fractures. We previously demonstrated that the posterior, anterior, and middle facets could be instrumented with two transducers. We also demonstrated that it was appropriate to apply load through both the tibia and fibula to simulate the *in vivo* situation.

Methodology—Fresh-frozen cadaver specimens, transected 20 cm above the tibial plafond, were used. Specimens were dissected down to the remaining osteoligamentous ankle and hindfoot specimen with intact soft tissues above the rest of the foot. Transducers were placed in the posterior, anterior, and middle facet as before, and the specimen was loaded. The talar neck was then osteotomized and

held in a nondisplaced position with a miniature external fixator and Kirschner wires. The specimen was then loaded again in a similar fashion. The talar neck osteotomy was subsequently displaced 2 mm in each of the following directions: medial, dorsal, lateral, and complex. The complex deformity was a 2 mm wedge creating varus deformity as well as 2 mm of dorsal displacement. In each case, when repositioning was performed the fixation was stabilized by moving the pins and fixator and tightening the frame.

Results—The mean total contact area in the posterior facet did not change significantly after osteotomy in the nondisplaced configuration. Following displacement, the smallest change was produced by a 2 mm medial translation of the neck on the head, and the largest change was due to complex misalignment; however, none was statistically significant. The mean high pressure zone in the posterior facet also did not vary significantly. The shape of the contact print changed, however, in four of the seven specimens. The contact area became more localized and discreet.

The effects on the anterior and middle facets were statistically significant. They decreased significantly with lateral displacement and with dorsal displacement of the neck on the head. More significant was the loss of high pressure zone from $24 \pm 16 \text{ mm}^2$ in the intact specimens, to as low as $1 \pm 3 \text{ mm}^2$ with dorsal displacement of the talar neck. The ratio of load distribution between the anterior,

middle, and posterior facets also changed. There was considerably more unloading of the anterior and middle facet than of the posterior facet, which suggests that the subtalar joint follows the position of the posterior facet rather than that of the anterior and middle facet.

Future Plans—We will continue to use this model to study further displacements of talar neck fractures, calcaneus fractures, and calcaneal osteotomies.

[46] Effect of Exercise on Growing Long Bones

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Sponsor: VA Rehabilitation Research and Development Service (Core Funds); National Aeronautics and Space Administration

Purpose—The mechanical behavior of whole long bones is determined by both geometry and material properties. It is commonly accepted that alterations in the *in vivo* mechanical loading of the skeletal system result in changes in bone mass and mechanical properties such as strength and stiffness. However, the relationships between changes in bone mass and alterations in bone strength and stiffness are not understood. The goal of this project is to develop a scaling relationship relating material properties and geometry to structural behavior in long bones during growth. Understanding how tissue and geometry change during growth will give insight into the processes underlying normal development. In addition, knowledge of these interactions may ultimately allow prediction of bone strength.

Methodology—A voluntary running model is being used to explore the interaction between bone tissue properties, geometry, and structural behavior in rat bone. Sixty male Sprague-Dawley rats were randomly assigned at 6 weeks of age to a sedentary group or an experimental group with free access to a running wheel. The distance run by the experimentals was monitored and recorded. Upon sacrifice both femora were harvested. Gross bone measurements (length, width, wet weight, volume) were taken and then the bones were frozen pending further analyses.

Histomorphometric analyses will be performed on the right femur and mechanical testing on the left. The sectional properties will be determined from a transverse thin section taken at mid-diaphysis of the right femur. After appropriate

processing, the area and moments of inertia will be determined.

Bone failure strength will be determined from a torsion test. This test is preferable to a bending analysis, for it is a measure independent of specimen orientation. From this test we will obtain torsional rigidity, maximum shear stress, shear modulus, ultimate torsional moment, and angle of twist. This testing will be performed on a servohydraulic MTS machine with a conversion jig to create the torsional couple.

In addition, in a separate analysis, the bone mineral content (BMC, g/cm) and bone mineral density (BMD, g/cm²) will be determined by single photon absorptiometry. Measurements sites are the proximal, mid, and distal segments of the tibia and femur.

Results—All gross bone measurements were significantly greater in the experimental group than in the controls ($p < 0.001$) and were positively correlated with body weight and age. The significance was retained by an analysis of covariance adjusting for age and weight. Femoral midshaft cross-sectional area was greater in runners than in controls ($6.26 \pm 0.1 \text{ mm}^2$ versus 5.45 ± 0.3 , $p < 0.02$) and remained significant when an analysis of covariance was used to correct for age and weight. The polar moment of inertia was also greater in runners than in control animals ($15.6 \pm 0.6 \text{ mm}^4$ versus 12.7 ± 0.2 , $p < 0.05$). The BMC and BMD were found to be higher in the runners than in the sedentary controls at all sites except the distal femur. However, within the experimental group, no positive correlation was

found between distance run and BMC, BMD, cross-sectional area, or polar moment of inertia.

Future Plans—Preparations for the mechanical testing are underway. Future work will examine the

effects of unloading on the structural behavior of long bones.

Recent Publications Resulting from This Research

Effects of Voluntary Exercise on Bone Mineral Content in Rats.
Newhall KM, et al., J Bone Min Res 6(3):289-296, 1991.

[47] Characterizing the Orientation of Cancellous Bone

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Sponsor: VA Rehabilitation Research and Development Service (Core Funds)

Purpose—One common way of characterizing the orientation of cancellous bone is to obtain a section of the trabecular bone, overlay it with a mask of parallel lines, and measure the mean "intercept length" (MIL) as a function of orientation angle. The results are typically presented in polar form and called a "rose plot." The difficulty with this approach is that the rose plots tend to have very broad maxima (peaks) making it difficult to determine the major orientation directions. Furthermore, it is common for the MIL plot to be fit to an ellipse. Because the principle axes of an ellipse are orthogonal, this technique is based on the condition that the material being studied possess orthogonal directions of orientation. This condition must be verified when applied to cancellous bone.

For the past 100 years, the trabecular structure of cancellous bone has been under study. It has been realized that the local mechanical stresses experienced by the bone somehow influence its structure so that the trabecular orientation is well suited to support this load. To study this relationship, it is necessary to mathematically characterize trabecular orientations. The goal of this research is to develop a new method of doing this that is more accurate and simpler to use than traditional stereological techniques.

Progress/Methodology—It is possible to "decompose" the rose plot into a number of characteristic functions, each of which corresponds to a single direction of orientation. This is achieved through the use of nonlinear programming techniques to determine the optimal set of functions needed to recreate the rose plot.

Portions of the human femur and calcaneus bones have been selected to evaluate this new technique. The bones are being embedded, sectioned, stained, digitized from photomicrographs, and analyzed with a computer implementation of the new technique. This will provide quantitative data describing the orientation of cancellous bone. Currently, appropriate specimens have been secured and are being prepared to be sectioned.

Future Plans—After this method has been verified in the above described experiment, it will be utilized in developing a theory governing the response of trabecular bone to applied mechanical loads. In particular, the relationship between local stress directions and the directional character of trabecular morphology will be studied.

[48] Chondrocyte Cell Culture and Mechanical Loading

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Sponsor: VA Rehabilitation Research and Development Service (Core Funds)

Purpose—The objective of these studies is to test the hypothesis that intermittent hydrostatic pressure will modify articular chondrocyte metabolism at the level of gene expression and extracellular matrix synthesis.

Progress—Continued studies on the effects of hydrostatic pressure on articular chondrocytes have focused on development of techniques for detection of changes in the extracellular matrix molecules. The goal remains to have the ability to quantify the state of the chondrocyte and the extracellular matrix at the closest possible moment to the point in time at which the loading condition is relieved. Previous studies addressing the question of hydrostatic loading of chondrocytes used guanidinium isothiocyanate extraction of total cellular RNA as a mechanism for capturing the state of transcriptional products. Those studies established that mRNA levels for proteoglycan and type II collagen are elevated in response to intermittent hydrostatic pressure. The influence of the intermittent hydrostatic pressure on chondrocytes varied with the inclusion of serum in the cell culture medium.

Methodology—In experiments carried out to date, the use of immunohistochemical techniques has been applied to capture the cellular responsiveness to mechanical loading histories. The procedure included a period of loading of the articular chondrocytes cultured as high density monolayers. The pressure was applied under physiological conditions of 1500 psi both as a constant load and as an intermittent load at a frequency of 1 Hz. The duration of loading was for 4 hours. At the conclusion of the loading period, the cells are fixed using paraformaldehyde in PIPES buffer. Following fixation, the cells are rinsed three times with phosphate buffered saline (PBS) and treated with

monospecific polyclonal antibodies prepared in rabbits against type II collagen and proteoglycan core protein. In all cases, a rabbit nonimmune serum serves as the rabbit IgG control. After specific labeling for 1 hour at 25 C, the rabbit antibody is removed. The cells are then treated with an FITC-labeled goat antibody preparation that is specific for rabbit IgG. Following a period of 30 minutes for binding, the cells are subsequently washed in PBS and overlaid with a solution of PBS/glycerol (1:1). The distribution of extracellular matrix molecules between the outside and inside of the chondrocytes is determined by permeabilizing samples to antibody using the nonionic detergent, Triton X-100.

Results—The analysis of the extracellular macromolecules has been carried out using phase contrast and fluorescence microscopy to determine the deposition of antibody to large aggregating proteoglycan and type II collagen in the cellular monolayers. Three separate experimental runs have been completed and the immunohistochemical techniques reveal staining of type II collagen and proteoglycan in the cell monolayers. Differences between the levels of fluorescence of the monolayers subjected to different loading conditions are under study and will be quantified using digitization techniques for analysis of the light emissions.

Future Plans—Experiments will be carried out to confirm the results obtained with the immunohistochemical procedures using cells cultured in medium containing 1 percent fetal bovine serum. Methodological approaches will be developed for the comparative quantification of the level of staining of type II collagen and proteoglycan using digitization techniques and statistical methods for data analysis.

[49] Bone Material and Structural Analysis

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Sponsor: VA Rehabilitation Research and Development Service (Core Funds)

Purpose—The objectives of this project include the determination of the fatigue and creep behavior of bone tissue and long-bone structures, the correlation of bone fatigue and creep characteristics with microstructural and molecular events leading to fracture, and the development of a phenomenological model to predict bone fracture. An understanding of the microstructural and molecular behavior of bone under various loading histories may influence orthopaedic treatment, procedures, and rehabilitation protocol. Results from these studies will provide basic material properties and behavior for use in the design of implants, joint replacement systems, and bone remodeling algorithms currently being used within and without our research group.

Methodology—The research plan is to conduct fatigue and creep tests on human machined cortical bone specimens and long-bone structures. Microstructural features associated with failure of the specimen or structure will be studied and mathematical models developed to characterize the mechanical and microstructural behavior.

Material and structural tests will be performed using MTS 810 and 858 mechanical loading systems. Machined cortical bone specimens will be tested using a variety of loading histories. Tensile, com-

pressive, and combinations of tensile and compressive cyclic and static loads will be applied in an attempt to define some fundamental components of bone material behavior in response to these loads. Stress, strain, modulus, and energy loss will be monitored with time. Specimen fracture surfaces will be studied using a Scanning Electron Microscope (SEM) to correlate macroscopic behavior with microstructural response. Whole long-bone structural tests will be conducted using four-point bending applied to the long-bone shaft. Cyclic, static, and combinations of cyclic and static loads will be applied and changes in structural properties with time will be monitored. Fracture features will be studied using an SEM.

Preliminary Results—Results from the tests have enabled the development of mathematical models of bone material behavior and allowed the prediction of material response to a given loading history.

Future Plans—Whole bone structural behavior and fracture features will be integrated with the results of the material tests to provide a holistic model to predict whole bone failure for a given loading history.

[50] Analysis and Simulation of Upper Limb Movements

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Sponsor: Easter Seal Research Institute of Ontario; Canadian Paraplegic Association

Purpose—One of the objectives of this research was to examine some of the kinematic and kinetic characteristics of unconstrained point-to-point three-dimensional (3-D) arm movements to try and determine if movements are planned at the hand or joint coordinate frame levels. Also, the initial and final positions of the hand were varied in order to study the effects of hand position, and therefore different

task requirements, upon the kinematic and kinetic timing characteristics of the shoulder, elbow, and wrist joints. Any resulting predictable variations or invariant dynamic characteristics may help to identify upper-limb movement control mechanisms.

A second objective of this research was to critically examine some of the kinematic and kinetic parameters of upper-limb motion to determine if

their characteristics correspond to those which would arise if optimization theory is being used by the CNS to plan voluntary arm movements. The validity of the proposed optimization functions were judged by comparing the predicted optimal values with the experimentally observed general temporal and shape characteristics of the kinematic and kinetic parameters of coordinated upper-limb movements. The various kinematic and kinetic parameters were also examined for any predictable temporal or shape characteristics which might help identify some other possible planning strategies.

Additionally, an approach based on artificial neural networks modeled after neuroanatomy and neurophysiology is presented as a way of explaining the behavior of upper-limb movements. It is hoped that learning a few typical movements within a class will lead to a transfer of learning to other movements within the same class (i.e., generalization), and that some of the observed invariants of arm movements will emerge through network interaction.

Progress/Methodology—Three right-hand dominant males performed three different reaching movements at two different speeds, with one of the movements repeated on different days. These movements were

unconstrained 3-D point-to-point motions under varying conditions of target location with initial and final positions having been specified. These particular movements were selected because they resemble the activities of daily living (ADL) movements which are used when objects are brought toward the body or when feeding occurs. All movements were kept away from the limits of the work space in order to prevent singularities and to eliminate results which would be directly affected by the position of the upper-limb at its boundary limits. No external disturbances were present during the movement. All of the movements were practiced at both speeds before data collection began. Data were collected for five repetitions of each motion at both speeds.

Subjects were seated and were instructed to perform a particular movement at a comfortable self-paced speed for the first five repetitions and then they were instructed to move as fast as possible on the next five repetitions of the same movement. Subjects were told to look straight ahead and not to visually guide their movements. No instruction was given about the form of the path or trajectory and no accuracy constraints were placed on the movements. The start and end of the motions were identified by an electronic on/off switch located on the middle and index fingers of the hand.

[51] Prediction of Bone Adaptation Based on Damage and Repair in Bone

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Sponsor: EOLAS—The Irish Science and Technology Agency; Johnson and Johnson Orthopaedics; Royal College of Surgeons of Ireland Research Fund; Health Research Board of Ireland

Purpose—The long-term objective of this research is the development of predictive models for bone adaptation with a view to applying them to the design of prosthetic implants. A method for the prediction of the time-course of bone adaptation based on an alternative hypothesis of strength optimization is investigated and developed into a working mathematical model. The model is based on the observed mechanics of bone fracture *in vitro*. It is planned to extend the theoretical basis of the model by further investigation of multiaxial damage mechanisms *in vivo*.

Progress—We have been studying methods to predict bone adaptation for the last four years and have shown that the damage/repair model can give physically reasonable predictions. The next phase of the research is to establish the model on a more rigorous footing. Two branches of work are in progress. The first is to use the damage/repair model to predict the bone adaptation that has been observed in animal experiments: an anatomical finite element model of the sheep's forelimb has been generated for this purpose. The second is a study of the damage development in bone under

increased and reduced stress and to investigate the existence of a distribution of damage within the bone at remodeling equilibrium.

Methodology—Our work is based on a close interaction between a materials science study of bone and the methods of computer analysis. Central to this is an attempt to develop a theoretical model for bone adaptation mechanistically using micromechanical variables that can be used in computational models.

Results—The development of a micromechanical model has been completed and the results predict that, after a change in stress, remodeling does result in the stress to converging directly to a homeostatic value; rather, the stress values oscillate about equilibrium. The model has been implemented using finite element analysis. Specifically, a finite element model was used to calculate the stress in an intramedullary fixation where it was predicted that intramedullary stems manufactured from low modulus materials will reduce proximal bone loss, whereas a prosthesis collar will not.

Future Plans/Implications—It is proposed to investigate the validity of the model in two areas. The

first is to simulate remodeling following controlled changes in the stress pattern in living bone. Both analytical and experimental models will be used. The second is to carry out microscopic observations of damage mechanisms in living and cadaveric bone subjected to known stress patterns. This will allow us to refine the mathematics of the model in the light of physical mechanisms of damage accumulation.

Recent Publications Resulting from This Research

- The Effect of Prosthesis Orientation on Stress Shielding Using Finite Element Analysis: Indications as to Bone Remodelling. Prendergast PJ et al., in *Interfaces in Medicine and Mechanics*, K.R. Williams, et al. (Eds.). London: Elsevier Applied Science, 329-339, 1990.
- A Stress Analysis of the Proximo-Medial Femur After Total Hip Replacement. Prendergast PJ, Taylor D, *J Biomed Eng* 12:379-382, 1990.
- A Structural Analysis of the Artificial Hip Joint. Prendergast PJ, PhD diss., University of Dublin, 1991.
- La Previsione Computerizzata del Rimoddlamento Dell'osso Nelle Protesi Intra-Midollari Usando Una Sollecitazione Micro-Meccanica. Prendergast PJ, Marcacci M, Fadda M, *Atti VIII Congresso Nazionale Della SIBOT*, Ferrara, 7-8 Giugno (in press).
- Theoretical Prediction of Bone Adaptation Using Damage Accumulation. Prendergast PJ, Lee TC, Taylor D, *J Anat* (in press).

[52] Quantitative Functional Anatomy of the Human Shoulder

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Sponsor: *Innovative Research Programme/Aids for the Handicapped*

Purpose—Quantitative data on the musculoskeletal system of the shoulder and arm are needed with a view to: 1) analysis of movements of shoulder girdle and arm, based on arm movement registration in activities such as wheelchair driving; 2) analysis of the movements of the shoulder girdle and arm in activities of daily living (ADL) and vocational activities; 3) analysis in the mechanics of shoulder luxation syndromes; 4) analysis of the outcome of arthrodesis of the shoulder; and, 5) aiding interpretation of *in vivo* human palpation data.

Progress—The cadaver measurements data were used to run a model which is based on finite element

analysis and comprised a dynamic version of this method (SPACAR). The model was used to describe the movements of the bones of the shoulder girdle and arm with respect to each other, and with respect to the trunk. The data of force exertion on wheelchair hand-rim were analyzed in terms of muscle strains. Statements on muscle function were formulated. They were mostly in accordance with classical kinesiology. It was concluded that the model is useful.

Future Plans—We plan to use the model in orthopaedic pathology, rehabilitation (wheelchair propulsion and ADL), and ergonomics.

Recent Publications Resulting from This Research

The Shoulder Girdle: Analyzed and Modelled Kinematically. Pronk GM, PhD diss., Faculty of Mechanical Engineering and Marine Technology, TU Delft, The Netherlands, 1990.
Inertia and Muscle Contraction Parameters for Musculoskeletal

Modelling of the Shoulder Mechanism. Veeger HEJ, Van der Helm FCT, Van der Woude LHV, Rozendal RH. *J Biomech* 24(7):615-629, 1991.

The Palpator: An Instrument for Measuring the Positions of Bones in Three Dimensions. Pronk GM, Van der Helm FCT, *J Med Eng Technol* 15(1):15-20, 1991.

[53] Quantitative Measures of Hand/Wrist Motions

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Sponsor: National Institute on Disability and Rehabilitation Research

Purpose—The objective of this ongoing study is to quantify motion characteristics of the wrist for a group of noninjured persons and a group of subjects afflicted with one or more diagnosed hand/wrist disorders of the cumulative trauma nature (i.e., carpal tunnel syndrome (CTS) or tendinitis). Assessment of such disorders is currently limited to palpation, static positioning methods such as Phalen's test, and nerve conduction velocity testing. This study seeks to develop a supplemental assessment tool for objectively quantifying motion deficits, which might be utilized in diagnosis and during treatment, and would be more closely related to task performance than current evaluation methods.

Progress—One goal is to identify differences in various kinematic measures between the performances of injured and noninjured subjects tested during performance of cyclic radial/ulnar motions with wrists deviated to five specific flexion or extension angles. Subjects wear two wrist monitors (electrogoniometers developed in the Ohio State University Biodynamics Lab) on each wrist: one for radial ulnar-motion, the other for flexion-extension motion. Sixteen noninjured and four injured subjects have been tested under variations of the test protocol. Originally, subjects performed repetitive motions in flexion-extension as well, but no differences in kinematic characteristics were seen between different fixed radial or ulnar postures.

Preliminary Results—Data are being examined at a descriptive level due to the small number of injured subjects. Peak and mean position, velocity, acceleration, and deceleration values are computed for each test condition. Although comparisons are made with caution, due to the aforementioned variations

in protocol among subjects, we do see differences in performance characteristics associated with the radial-ulnar repetitions between the two groups. Magnitudes of position amplitudes in both the radial and ulnar directions are lower in all instances for the injured group compared with the noninjured group. Similar results occurred between the two subject groups for the peak radial velocity and acceleration data. Patterns within the two groups are similar across test conditions. At more extreme fixed postures, all motion parameters are reduced; greater amplitudes, speeds, and accelerations occur at the more neutral deviations.

Data are also examined from a phase plane perspective (velocity versus position, rather than time). These measures describe the degree of smoothness of the phase plane representation and the repeatability of the phase plane over the data collection period. Timing of the phases of motion are examined, as are variations in that timing. At this point, there do not appear to be strong differences between injured and noninjured groups for any of these measures, except possibly for the cycle time variation measure, which is greater for the injured hands.

Future Plans—The main goal for the next period is expansion of the subject database. We intend to initiate longitudinal testing of injured subjects, if suitable subjects are found. Once a sufficient number of injured subjects are tested, we will commence statistical comparison testing of injured and noninjured group data. We anticipate winnowing the number of motion characteristics currently evaluated to a few key parameters which will describe performance and group subjects correctly.

Implications—This research is expected to provide information regarding dynamic characteristics of the wrist joint for injured and noninjured persons. It is anticipated that this information may be used to differentiate persons into one of those two groups,

and may lead to distinctions between wrist disorders within the injured group. This research is expected to yield an objective testing procedure for evaluation of rehabilitation progress for those being treated for a hand/wrist disorder.

[54] Vermont Rehabilitation Engineering Center: Low Back Pain Studies

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—The Vermont Rehabilitation Engineering Center (REC), now in its second 5-year funding cycle, is committed to improving the prevention, treatment, and rehabilitation of low back pain through an integrated program of basic and applied research and information services. Specific objectives of this multidisciplinary center include: identification of risk factors for low back injury, pain, and disability; development of new measurement methods for diagnosis and research; evaluation of treatment programs and modalities; worksite assessment and modification; service delivery; and, information dissemination and training. Affiliates of the Vermont REC include the Spine Institute of New England, which operates a comprehensive rehabilitation program for chronic low back patients, and Rehabilitation Technology Services, which provides service delivery to people with low back and other disabilities. The Vermont REC also maintains a formal collaborative agreement with the University of Goteborg and Chalmers Institute of Technology in Sweden.

Projects/Progress—Several research projects are currently under way in the following areas:

Prediction of Disability and Assessment of Rehabilitation Strategies. *Larry D. Haugh, PhD.* The REC has continued its pioneering work on prediction of low back disability. A model has been developed that predicts disability outcome with 83% to 89% accuracy and a questionnaire based on this model has been developed and refined.

Intervertebral Motion and Muscle Use Detection. *Martin Krag, MD.* This project was designed to develop a methodology for characterizing intervertebral motion and muscle use patterns in the lumbar spine. The design and fabrication of equip-

ment and software has been completed, and *in vivo* testing is underway.

Lifting Capacity. *Rowland Hazard, MD.* A prototype device for measuring lifting ability has been developed. The device, which incorporates an assessment of subject effort, promises to be a practical, reliable, and inexpensive means of determining lifting capacity for a wide range of occupational health practitioners.

Exercise and Physical Conditioning. *Mary Moffroid, PhD.* This project comprises several discrete studies designed to study the endurance and eccentric capability of the muscles surrounding the lumbar spine. Long-range goals include designing effective measurement tools and treatment programs.

Evaluation of Biofeedback in Lumbar Orthoses. *Leon J. Grobler, MD.* Lumbosacral corsets are frequently prescribed for low back pain, although their effectiveness and mechanisms of action have not been demonstrated. Research is being conducted to compare the effectiveness of auditory feedback, trunk inclination feedback, and EMG feedback. The project comprises design and testing of devices and two triple crossover studies.

Seating Studies. *Steven Reinecke, MSME.* A continuous passive motion (CPM) device that promotes movement of the lumbar spine during seated tasks has been designed. The device is now being tested to determine its efficacy in minimizing back discomfort in both static (office) and vibrational (vehicle) seating environments. An adjustable sit-stand workstation has also been designed and is being tested by back-healthy subjects as well as back pain patients to assess its effect on subject fatigue, comfort, and productivity.

Vibration Studies. *David Wilder, PhD.* With a long-range goal of optimizing work environments that involve vibration, this project was designed to assess the relative contributions of various spinal support structures, seating components, and postures to fatigue and back pain. Worksite assessments are frequently performed to measure amounts of vibration and impact, and recommendations made to minimize their deleterious effects on the spine.

Development of a Workload Assessment System. *Jerry Weisman, MSME.* A Workload Assessment System (WAS) is being developed to provide detailed information about various biomechanical stresses in the workplace. Posture and load can be monitored continuously over the course of the day and analyzed to provide a picture of job task demands. The system will be used to assess job demands across several occupations, in Vermont and elsewhere.

Information Services. Publications: *Antonia Clark, MS; Public Relations: Janice Clements, BS; Bibliographic Research and Services: Elizabeth Dow, PhD.* The Information Services Division of REC comprises a variety of activities in information and referral, publications, education and training,

public relations, and research evaluation. The Vermont REC offers assistance in locating programs and provides information search services.

Recent Publications Resulting from This Research

- Factors Affecting the Dynamic Response of the Seated Subject. Pope MH, Broman H, Hansson T, *J Spin Disord* 3(2):135-142, 1990.
- Occupational Low Back Pain (2nd Edition). M.H. Pope, J.W. Frymoyer, G.B.J. Andersson, D.B. Chaffin (Eds.). Chicago: C.V. Mosby Co., 1990.
- Rehabilitation Technology in the Workplace. Weisman J, in *CRC Handbook of Rehabilitation Engineering*, J. Leslie (Ed.). Boca Raton, Florida: CRC Press, 1990.
- Rehabilitation of the Patient with Chronic Low Back Pain. Hazard RG, et al., in *Occupational Low Back Pain* (2nd Edition), M.H. Pope, J.W. Frymoyer, G.B.J. Andersson, D.B. Chaffin (Eds.). Chicago: C.V. Mosby Co., 1990.
- Dynamic Lifting Capacity: The Relationship Between Peak Force and Weight as an Indicator of Effort. Hazard RG, et al., *J Spin Disord* 4(1):63-67, 1991.
- Isokinetic Trunk-Strength Deficits in People With and Without Low-Back Pain: A Comparative Study With Consideration of Effort. Reid S, Hazard RG, Fenwick JW, *J Spin Disord* 4(1):68-72, 1991.
- A Technique for Needle Localization in Paraspinal Muscles with Cadaveric Confirmation. Haig AJ, et al., *Muscle Nerve* 14:521-526, 1991.
- Whole-Body Vibration Exposure in Subway Cars and Review of Adverse Health Effects. Johanning E, et al., *J Occup Med* 33(5):605-612, 1991.

[55] Harvard-Massachusetts Institute of Technology Rehabilitation Engineering Center

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—The Harvard-MIT Rehabilitation Engineering Center addresses the NIDRR Research Priority "Quantification of Human Physical Performance." Seven collaborative, interdisciplinary projects (listed below) involve rehabilitation engineering research personnel at the MIT Newman Laboratory for Biomechanics and Human Rehabilitation and clinical rehabilitation research personnel at the Biomotion Laboratory of the Massachusetts General Hospital and at the Veterans Administration Medical Centers at West Roxbury/Brockton and Jamaica Plain.

- Computer-Aided Surgical Simulation of Femoral and Tibial Osteotomy
- Patient Management and Rehabilitation Protocols Following Major Hip Surgery Based on Quantitative *In Vivo* Data
- Quantification of Human Motor System Adaptation and the Ability to Use Hand Tools by Upper Extremity Amputees
- Quantitative Assessment of Functional Electrical Stimulated Grasp Devices Using a Human Interactive Hardware Simulator Approach

- A Force and Movement Transduction System for Diagnosis and Treatment of Movement Disorders
- Multi-Degree-of-Freedom Manipulandum for Characterization of Motor Function and Optimization of Assistive Technology
- Quantitative Assessment of Posture and Balance Abnormalities

All projects stress developing and evaluating scientifically-based, quantitative methods for assessing the physical status of handicapped persons and of therapeutic efforts for defect remediation. Different projects address medical interventions, including orthopaedic surgery and physical therapy, and/or augmentative technology including amputation prostheses, orthoses, and functional neuromuscular stimulation.

A theme common to all projects is the use of human-interactive computer-based systems for functional assessment of disability status. When employed diagnostically, such systems present perfor-

mance criteria and data via "friendly" computer interfaces to the physician, rehabilitator and/or subject. When the consequences of differential therapy are being evaluated, such systems emulate alternative assistive technologies using special-purpose hardware in conjunction with the computer system, thereby achieving physical interaction with the disabled person. Such quantitative assessment can critique, augment and enhance more common and prevalent qualitative, subjective, medical and rehabilitation assessments.

Inherent in our approach is the conviction that mathematically expressible (and therefore, computer manageable) models of augmentative technology, of aspects the disabled human and device-human interaction can help diagnose the extent and character of disability and better define and evaluate proposed rehabilitation protocols and technology. All studies are directed toward practical augmentative technology and/or improved rehabilitation diagnosis and therapy.

[56] Computer-Aided Surgical Simulation of Femoral and Tibial Osteotomy

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Purpose—In the hip joint, the degeneration of cartilage, synonymous with osteoarthritis, is usually focal and located on the superior region of the femoral head where it articulates with the acetabulum, the area loaded during the stance phase of normal level walking. In intertrochanteric osteotomy, the proximal section of the femur is transected and reoriented to move an area of good cartilage into the load-bearing region. The average 12-year life of total hip replacement has renewed interest in osteotomy since it is intrinsically conservative of joint tissue, compared with total replacement where the removal of much natural bone and the use of acrylic cement makes revision difficult. For the younger patient, a successful osteotomy can provide five, ten, or more years of service before partial or total hip replacement is necessary. At the knee, proximal tibial osteotomy is indicated in

patients with osteoarthritis of one tibiofemoral compartment producing varus or valgus deformity.

Methodology—The preoperative planning of either osteotomy procedure poses a substantial geometric and functional challenge to the orthopaedic surgeon. In current practice, planning is based on, at the most, biplanar X-rays of the affected region. Using a protractor, ruler, and grease pencil, the orthopaedic surgeon sketches on the two-dimensional X-rays a geometrical design of what is intrinsically a 3-D manipulation. In addition to the primary goal of cutting and reconnecting the fragments of the proximal femur or tibia to bring good cartilage into proper load-bearing, the surgeon must also ascertain that the proposed alteration will cause minimal interference with the normal ranges of motion about the joint. Further, he/she must be

confident that the alteration or reorientation of the bone components has not significantly lengthened or shortened the skeleton across the joint, considering also the possible alteration of the effective muscle or ligament lengths. Ultimately, the surgeon must be concerned with how the operation will affect, and hopefully improve, the mobility and grace of the subject in tasks such as normal level walking, stair-climbing, rising from a chair, etc. The magnitude and complexity of this design task undoubtedly explains, in part, the uncertain outcome of the procedure and represents a deterrence to more widespread practice of osteotomy.

Computer-aided surgical simulation (CASS), addresses this surgical design problem as prototypical of many musculoskeletal alterations practiced in orthopaedic surgery. CASS borrows from the now well-established field of computer-aided design (CAD), adopting both commercially-available computer hardware and graphic display terminals and reinterpreting and augmenting computer-aided design software.

Observation of surgeons and practice in orthopaedics suggests that the engineer-designer and the orthopaedic practitioner have much in common. They observe the circumstances of the situation and devise an idea for a solution. Whereas the engineer-designer now can carry out the exploration, iteration, and optimization of design concepts in consort with the computer, the surgeon practitioner is constrained to a single solution, the particular surgical procedure performed in the operating room, and then must await the recovery of the patient to observe the consequences. Validation is uncertain since many procedures are very patient-specific. Even with similar procedures, the surgeon must follow a series of patients before evaluation of outcome is possible.

In some aspects, CASS is significantly different than CAD. Whereas the engineer designs *de novo*, the surgeon must deal *a priori* with the patient-specific, complex geometry of the relevant skeletal anatomy. The surgeon devises a plan to sever, realign, and reconnect these anatomical parts, then wants to explore the consequences of the changes, compared to the preoperative state of the patient. A further major distinction between the design engineer with a CAD system and a surgeon simulating a procedure on the patient's anatomy with the CASS system is the background and experience the respective operators bring to the computer system. The engineer is fluent in the geometric, mathematical, and physical implications of CAD manipulation and is familiar with computer hardware and software. The surgeon's relevant prior experience focuses on direct observation and examination of the patient and studying the X-rays. Therefore, the computer's graphic display must present anatomy and mobility to the surgeon in a manner consistent with his or her prior experience; and the means by which the surgeon manipulates the display and interprets the consequences of changes must be as traditional and easy to learn as possible.

Results—Overall, CASS can be subdivided into three tasks: mobility analysis for presimulation recording and presentation of user-friendly, easily manipulable and interpretable dynamic displays of the patient's movement patterns; patient-specific anatomical representations for the computer displays on which the surgeon will simulate and evaluate the procedure and for the determination of body segment mass and inertial properties for dynamic analyses; and musculoskeletal modelling for the detailed mathematical representation of the skeletal, joint, and muscle system for pre- and post-simulation evaluation.

[57] Measurement of the Degrees of Freedom of the Normal Human Knee In Vivo

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Sponsor: *National Science Foundation*

Purpose—Modelling is an essential tool for evaluating the dynamics and control of the human knee. A prerequisite to the development of a mathematical model of the knee is the complete characterization of the kinematics of the joint, *in life*, in particular, the number of kinematic degrees of freedom. While *in vitro* experiments on cadaver knees are reported, there is a dearth of detailed, confirmed *in vivo* lower extremity skeletal kinematic data reported in the literature. Much of the existing data are for only a single activity, level walking. Inadequate information about the motion of the knee under different movements and loads has led to the proposal of knee models ranging from a single degree of freedom to four degrees of freedom. The goal of this study is an experimental data-based, mathematical model of the normal human knee capable of predicting the kinematics resulting from various pathological activities, and thus amenable to studying knee pathologies, evaluating contemporary internal prostheses and external orthoses and recommending new designs for knee augmentation or replacement.

Methodology—The control of the normal knee was investigated via experiments to measure its kinematics during several different tasks performed by a single subject. Arrays of markers—infra-red LEDs—were mounted on pins inserted with the skeletal bones and the TRACK kinematic data acquisition system used to measure the bone movements about the knee. Data were collected for voluntary swing of the knee through its full range of motion, normal gait, and a pivoting motion common in athletics. Three-dimensional marker coordinates were smoothed using the GCV based algorithm of Dohrmann and the rigid body orientation and position data were differentiated using a Lanczos filter to obtain velocities. The velocity data were then used to calculate the instantaneous helical axes (IHAs) of the different movements. The loci of the IHAs for a task define a pair of ruled surfaces, one

in the fixed body and one in the moving body. These surfaces are the axodes of the movement and are characteristic of the mechanism producing the motion. Axodes for the different tasks were displayed on a personal IRIS workstation.

Results—The results clearly show that normal knee motion is dependent upon the task being performed. The axode for the voluntary swing motion is that of a nearly planar movement with different trajectories for flexion and extension. Both normal gait and the pivoting maneuver are fully three-dimensional motions, each with a distinctly different sequence of IHAs. A joint or coupling such as the knee constrains the relative motion between two bodies. The allowable range of motions constitutes a screw system of an order equal to the number of degrees of freedom of the joint. The order of the system is determined by the number of independent screws in the system. Techniques are available for evaluating the independence of screws in a system and for determining an orthogonal basis for a screw system. The number of active degrees of freedom for each of the different tasks was evaluated in both ways.

Future Plans—In a second bone-pin experiment a 3-axis accelerometer mounted on each LED array will complement the TRACK position measuring system. Kinematic data will be processed both by smoothing and differentiating the position data and integrating the accelerometer input, with comparisons thereof. Data will be collected over a greater range of movements than the prior original bone-pin experiment and very specific protocols will be employed.

Recent Publications Resulting from This Research

Geometry of the Kinematics of the Normal Human Knee. Murphy MC, PhD diss., Massachusetts Institute of Technology, 1990.

Instantaneous Helical Axes of the Normal Human Knee in Vivo. Murphy MC, Zarins B, Jasty M, Mann RW, East/West Coast Gait Laboratories Conference, San Diego, 1990.

Measurement of the Degrees of Freedom of the Normal Human Knee In Vivo. Murphy MC, Mann RW, Proceedings of the Symposium on Dynamics and Control of Biomechanical Systems, 1990 ASME Winter Annual Meeting, Dallas, 1990.

[58] Using Axodes to Compare In Vivo Knee Kinematics Measured Using Bone versus Skin-Mounted Markers

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Sponsor: *National Science Foundation*

Purpose—Two problems inherent in biokinematic studies are: 1) whether skeletal motion is accurately measured by observing markers on the skin; and, 2) how to define body-fixed coordinate systems relative to skeletal segments. Typically, experimenters place markers on the skin over bony landmarks (i.e., locations where the skeletal members may be palpated through the covering soft tissue), with the implicit assumption that the marker motion is an accurate reflection of the underlying skeletal movement. Yet, several studies indicate that there are significant artifacts from soft tissue motion in kinematics measured with skin-mounted markers. However, quantitative information on the relative motion between the skin and bone is not available.

Methodology—A program of experiments was initiated to quantify any differences between the three-dimensional *in vivo* kinematics of the knee measured directly on the skeleton and corresponding measurements using several different schemes for mounting markers on the skin. To compare the mounting methods, the same subject was used in all experiments, and the same tasks were performed. When comparing data from different experiments, consistency in the representation of the data is essential. Thus, kinematic representations such as Euler angles are not acceptable. Euler angles, as well as most other methods used in biokinematic studies, are dependent on how body-fixed coordinate frames are defined. Since the definitions of these coordinate systems with respect to the skeleton cannot be performed with consistency, a different type of representation must be used. By calculating instantaneous helical axes and studying the resulting axodes, assembled from these time-varying axes, a descrip-

tion independent of coordinate frame definitions was obtained.

The experimental data were collected using the Selspot optoelectronic motion measurement system, with infrared LEDs used as markers, and the TRACK software. In the first experiment, the LEDs were mounted in groups of six on rigid Plexiglas arrays attached to skeletal pins placed directly in the tibia and femur of the subject. In subsequent experiments with the same subject, the arrays of markers were mounted on the subject using three different techniques: 1) taped directly to the skin over bony landmarks; (2) mounted on rigid acrylic frames strapped to the subject's limbs; and, 3) mounted on molded plastic forms held on the subject with a vascular stocking. Data were obtained for different tasks, including normal gait and voluntary swing of the knee through its full range of motion.

Results—Results of the bone-mounted markers for a voluntary swing show a nearly planar motion with different flexion and extension trajectories. The taped-on markers gave the least accurate reflection of this pattern, while the third mounting scheme produced a good representation. For gait data, the directly measured kinematics indicate a combination of planar motion and rotations about secondary axes. The skin-mounted markers showed a predominantly planar motion, and did not accurately measure out-of-plane rotation components. Discrepancies may be attributed to skin motion relative to the bone. Results thus far are for a single subject and need further confirmation.

Future Plans—A second bone-pin experiment will complement the existing database and provide an

opportunity to compare a wider range of skin-mounting methods for the marker arrays.

Recent Publications Resulting from This Research

Comparison and Analysis of Biokinematic Data Using Instantaneous Helical Axis Methods. Karlsson JOM, S.M. Thesis, Massachusetts Institute of Technology, 1990.

A Comparison of In Vivo Knee Kinematics Measured with Bone and Skin-mounted Markers. Murphy MC, Karlsson JOM, Zarins B, Jasty M, Mann RW, East/West Coast Gait Laboratories Conference, San Diego, 1990.

Using Axodes to Compare In Vivo Knee Kinematics Measured with Bone and Skin-mounted Markers. Karlsson JOM, Murphy MC, Mann RW, Symposium on Dynamics and Control of Biomechanical Systems, 1990 ASME Winter Annual Meeting, Dallas, 1990.

[59] Clinical and Biomechanical Evaluation of the Ischial Containment-Type Socket for Above-Knee Amputees: A Pilot Study

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Sponsor: Scottish Home and Health Department

Purpose—Considerable interest has developed internationally concerned with the ischial containment-type socket and its potential ascendancy over the quadrilateral or ischial bearing socket. The aim of this project was to carry out a clinical and biomechanical evaluation of the ischial containment-type socket for above-knee amputees, and compare its performance with that of the conventional ischial bearing type socket.

Methodology—Four relatively active male above-knee amputees have been fitted with a quadrilateral socket and an ischial containment-type socket. Two identical sockets were produced of both types for each patient—one being a normal socket incorporated into the delivered prosthesis, and the other manufactured complete with inserts to enable the attachment of pressure transducers. The normal prosthesis was delivered and worn by the patient for a 3-month period. The biomechanical test regime was performed at the beginning and end of each 3-month period.

The test protocol dictated that two days were required to complete the desired measurements. During Day 1, pressure measurements were obtained from the instrumented prosthesis, while kinematic and kinetic data were recorded using a Vicon TV movement analysis system and Kistler force platforms. Heel and toe footswitches were also employed. The second round of testing occurred the next day (or as soon as was practicable for the

patient), on the completed prosthesis, when full locomotion tests were carried out. Kinematic data from the lower limbs and trunk were collected using the Vicon system. The ground reaction forces were recorded using the Kistler force platforms. Thus, the movements of the limbs and the trunk and the loading on the various limb joints could be determined. Physiological studies consisting of heart rate monitoring and oxygen uptake were performed to assess the energy usage of the patient. Temporal-distance parameters were also recorded using an instrumented walkway.

Progress—Four patients have been fitted with both sockets. All biomechanical testing has been performed and completed on the first issued socket and all tests have been completed at the beginning of the second 3-month stage on the second socket. Completion of the second stage of the regime will occur shortly.

Results—As this is a comparative study and as yet incomplete, no results can be presented at this stage. Preliminary analysis of data required would suggest that significant pressure distribution differences are detectable, as are some differences in the measured parameters of gait. Subjective comments from the patients are overwhelmingly in favor of the ischial containment socket with observable improvements in skin coloration and condition.

[60] Three-Dimensional Biomechanical Model of the Shoulder Mechanism

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Sponsor: *None listed*

Purpose—The overall purpose of this project is to develop a three-dimensional (3-D) biomechanical model of the shoulder and shoulder girdle with which the effects of orthopedic treatment in the shoulder region can be predicted.

Methodology—With the help of the computer program Spacar based on a finite element approach, the shoulder mechanism can be modeled as a spatial mechanism consisting of beam, hinge, surface, truss, and slider truss elements, which describe the properties of the bones, joints, thorax, ligaments, and muscles, respectively. In that way, an inverse dynamic model of the shoulder mechanism, including 16 muscles, three extracapsular ligaments and the scapulothoracic gliding plane, has been developed. Muscles are represented by a number of straight or curved lines of action. For quantification and validation of the model, the following measurements were executed: 1) the 3-D positions of the scapula and clavicle were measured at several flexion as well as abduction angles of the humerus with and without loading the hand (30 subjects); 2) the 3-D humerus motions of 18 subjects with a glenohumeral arthrodesis were measured with the help of two video cameras; 3) a cadaver study in which the positions of the bones, the attachments of both ligaments and muscles, as well as the shape of all articular surfaces of 14 shoulder specimens were measured three-dimensionally; and, 4) with 12 surface electrodes, the EMG-activity of seven muscles was measured during humerus elevation with and without loading the arm (12 subjects).

Progress—The inverse dynamic model of the shoulder mechanism has been used to investigate the influence of the fusion position between the humerus and the scapula, as well as the role of the shoulder girdle muscles on positioning the hand after a glenohumeral arthrodesis. With the help of the kinematic model, the effect of physical therapy on the clavicle and scapula during mobilizing the glenohumeral joint in the case of a frozen shoulder has been examined. For the development of a dynamic model, a model of the neuromuscular system has been implemented in the finite-element method.

Future Plans—Next year, a major part of the project will be focused on analyzing the function of the muscles in the shoulder region by means of model simulations and experiments. Also, the influence of velocity on the motion pattern between clavicle and scapula will be studied with the help of 2-D roentgen cinematography. Parts of the model will be used to investigate the control mechanism of the rotator cuff muscles by which the glenohumeral joint is stabilized.

Recent Publications Resulting from This Research

Inertia and Muscle Contraction Parameters for Musculoskeletal Modelling of the Shoulder Mechanism. Veeger HJ, et al., *J Biomech* 24(7):615-629, 1991.

The Palpator: An Instrument for Measuring the Positions of Bones in Three Dimensions. Pronk GM, Van der Helm FCT, *J Med Eng Technol* 15(1):15-20, 1991.

The Shoulder Girdle: Analysed and Modelled Kinematically. Pronk GM, PhD diss., Delft University of Technology, 1991.

[61] Capture and Analysis of Joint Sounds

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Sponsor: *None listed*

Purpose—The purpose of this study has been to develop a low-cost computer-based system for the

capture of transient joint sounds, and to analyze these sounds for signs of disease or other joint

malfunction. Concentrating initially on dental occlusion and the temporomandibular joint, and using a low-cost personal computer with suitable signal interface, a second purpose of the study has been to examine the feasibility of using a standard cassette tape recorder in the clinic, then replaying the recorded sounds into the computer for analysis at a later time, making the technique accessible to general practitioners in both medicine and dentistry.

Progress—Since the last report, the capture system has been independently verified with a fast storage oscilloscope, using a split signal captured by both the oscilloscope and the development system. No detectable differences were found between either capture method. However, there have been several problems associated with the capture probe and the tape recorder, and not only has it been necessary to investigate these in detail, but the results suggest that unless other workers in this field take similar precautions their results may be spurious.

Methodology—The system being developed uses a BBC microcomputer to which is attached a Unilab interface (Unilab, UK). This low-cost interface is a general-purpose signal input/output unit containing a fast analogue-to-digital converter which allows rapid capture at a maximum sample rate of 125 kHz, although software restrictions in the current study reduce this figure by approximately a factor of 2. Signal detection is via a vibration transducer (Knowles Electronics, UK) rather than a microphone because it can be placed directly against the joint without picking up ambient noise. The captured signal is either fed directly to the interface and/or recorder, or may be preamplified if desired.

Preliminary Results—We have found that the resonance frequency of the transducer (ca. 12 kHz) may be mistaken for high frequency sound, putting an upper limit on the waveband for capture which is fortuitously similar to the upper frequency limit of normal cassette recorders. To prevent aliasing of this high-frequency component, with the consequent appearance of spurious low frequencies, the sampling rate must therefore be at least twice this value.

We have also found that inadvertent earth loops can simulate high-frequency sound, and the position of the sensor on the head can also affect the captured sound envelope. Of particular interest is the observation that the mass of the sensor attenuates higher frequencies, providing a simple mechanical means of filtering. More worrying is that tape recorders can have a nonlinear frequency response such that higher frequencies are attenuated, and this is currently under investigation so that the true sound envelope may be known. As part of this study we have separately found that the automatic gain control of modern tape recorders provides a progressive delayed gain which affects not only the part of the sound envelope which triggered it, but also several subsequent cycles in a nonlinear fashion. To avoid this, we are now bypassing the *agc* control, but others who may be considering tape recorders for signal capture may not be aware of the problem.

Any or all of these factors can lead to the recording of false or distorted sound envelopes, and we are now investigating them in detail, both in a general sense, and in relation to our particular experimental design.

B. Human Locomotion and Gait Training

[62] Insole Segmented Foot Pressure Measuring System

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Sponsor: VA Rehabilitation Research and Development Service (Project #A608-RA)

Purpose—The overall goal of this project is to develop a prototype foot-force measuring system

consisting of: 1) a foot-shaped force-sensing array; 2) associated sensor array electronics; and, 3) a

personal computer (PC) and software for controlling the operation of the sensor, displaying the foot-force information, and extracting key parameters from the data. When completed, the prototype system will be delivered to Rancho Los Amigos Research and Educational Institute for clinical evaluation.

Methodology—The foot-force measuring system is based upon technology developed by Bonneville Scientific, Inc. for robotic tactile sensing. A significant portion of this project entails adapting Bonneville's existing tactile sensing system to foot-force measurement. This adaptation includes modifications to the electronics to accommodate the larger foot-force sensor, and to convert to a PC-based system that requires much less computer literacy.

The foot-force sensing array uses a thin rubber pad which is deformed when an object presses into it. The amount of this deformation depends upon the magnitude of the forces applied to the pad and the stiffness of the rubber. Underneath this pad is a very thin two-dimensional array of ultrasonic transmitters and receivers which is used to measure the thickness (or image the surface) of the rubber pad. Thickness is measured by ultrasonic pulse-echo ranging. The round-trip travel time of the pulse is measured and is proportional to the thickness of the rubber pad overlying a particular force-sensing element. Typically, changes in pad thickness of a few microns can be detected. Depending upon rubber stiffness and array element size, forces of less than one gram can be detected.

Progress—A foot-shaped force-sensing array for a male size 10 shoe has been designed on our computer-aided design system. This array consists of three sub-arrays in order to simplify sensor fabrication.

These sub-arrays approximately correspond to the size and shape of the heel, arch, and fore-foot regions of the foot, and have 99, 90, and 395 sensing elements, respectively.

The right half of the fore-foot sub-array has been fabricated and tested. Test results showed that echo signals from many of the elements were weaker than expected. This problem was traced to adhesive layers in the sensor. The fabrication procedure was modified so that more clamping force could be applied to express excess adhesive during array assembly. A new sub-array is in the final stages of fabrication.

The electronics formerly used for operating robotic tactile sensors are being modified to address the greater number of elements in the foot-force sensor and also to reliably detect the weaker echoes that are expected.

Progress has been greater than expected in developing a 386-based PC system for operating the foot-force sensor. This computer operates under MS-DOS and uses Windows for the user interface. In order to speed software development, we are using an existing tactile sensor and its support electronics connected to the interface board in the computer to test software.

Preliminary Results—Software has been written for operating the sensor and displaying the force data. Preliminary results indicate that with the almost 600-element foot-force sensor the following performance will be possible: 1) the entire array can be scanned and the resulting force data stored in computer memory at the rate of 100 scans (or frames)/sec; 2) these data can be "played back" and graphically displayed at approximately 3 frames/sec; and, 3) over 100 seconds of data can be taken during one interval.

[63] Pathokinesiology of Anterior Cruciate Ligament Deficiency

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Sponsor: VA Rehabilitation Research and Development Service (Project #A178-3RA)

Purpose—The objective of this project was to investigate the deviations from normal kinematics,

ground reaction forces and muscle function in subjects with knees having a ruptured anterior

cruciate ligament (ACL) and to investigate the kinematics of the surgically reconstructed knee. Measurements were made using 6-degree-of-freedom goniometry, a biomechanics platform, and electromyography during walking and pivoting.

Progress/Methodology—The knee kinematics and muscle patterns of 16 individuals with surgically reconstructed knees have been added to the database containing this information from 25 individuals with uninjured knees and of 20 individuals with injured knees. The kinematics were quantitated using helical motion analysis. The most difficult part of assessing and explaining the abnormal knee motions has been representing them in terms of anatomic variables in addition to helical motion variables. A technique has been developed which compares the motions of individual knee joints with respect to a composite normal profile and expresses any differences in anatomic variables.

Once the differences have been calculated it is necessary, because of population variability, to ascertain whether any differences are significantly different. A large effort has been expended to study the appropriateness of various parametric and nonparametric statistical tests that could provide this information. Sufficient testing indicates that the population data of helical motions is Gaussian and populations can be compared using the Behrens-Fisher algorithms for unequal group sizes and unknown mean vectors and covariance matrices.

A pattern analysis technique has been developed to determine the differences between normal muscle activity and activity in individuals with ACL deficiency.

Results—The statistical testing of the kinematics shows that tight injured knees have kinematics resembling uninjured knees whereas loose injured knees are vastly different. The kinematics of surgically reconstructed knees are more normal than those of loose injured knees but not as "normal" as those of tight injured knees.

The muscle patterns of subjects with injured knees developed during free-speed walking are not different from normal. However, during fast-speed walking there are many differences that are observed as time shifts in major phases of activity, absence of second phases, and additional phases of activity. Synergy analysis reveals that if one muscle has an atypical pattern, then several do; that is, ACL injury induces major changes in the control strategy of the knee joint.

Recent Publications Resulting from This Research

- Quantitative Representation of Electromyographic Patterns Generated during Human Locomotion. Shiavi R, IEEE Eng Med Biol 9(1):58-60, 1990.
- Clustering Analysis and Pattern Discrimination of EMG Linear Envelopes. Zhang L, Shiavi R, Hunt M, IEEE Trans Biomed Eng 38:777-784, 1991.
- Electromyography Profiles of Knee Joint Musculature during Pivoting: Changes Induced by Anterior Cruciate Ligament Deficiency. Limbird T, et al., J Electromyog Kinesiol 1:49-57, 1991.
- Reaction Force Patterns of Injured and Uninjured Knees during Walking and Pivoting. Hasan S, et al., J Electromyog Kinesiol 1:218-228, 1991.
- Pattern Analysis of EMG Linear Envelopes Exhibited by Subjects with Uninjured and Injured Knees during Free and Fast Speed Walking. Shiavi R, et al., J Orthop Res (in press).

[64] Effect of Walking Cadence on Plantar Pressures

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Sponsor: VA Rehabilitation Research and Development Service (Project #A624-RA)

Purpose—The purpose of this project is to evaluate the effects of different walking cadences on the in-shoe plantar pressures from nondisabled subjects.

Methodology—The objective of this study was to evaluate the effect of different walking cadences on

plantar pressures. Seven able-bodied subjects (mean age: 32, mean body weight: 77 kg, and mean height: 1.78 m) were studied. All subjects demonstrated no gait disorder and their feet were free from ulcers and deformity. Seven pressure sensors were placed in the left and right insoles under the metatarsal heads,

hallux, and posterior and anterior heels. The subjects walked on a 32-meter walkway at controlled cadences of 70, 80, 90, 100, 110, and 120 steps/minute respectively. At each cadence, 4 minutes of pressure data during continuous walking were collected; and peak pressures at all 14 locations were processed for each step.

Results—Compared with pressures at the cadence of 70 steps/minute, mean peak pressures increased up to 20.9% at 80 steps/min, 37.5% at 90 steps/min, 57.5% at 100 steps/min, 75.5% at 110 steps/min, and 116.7% at 120 steps/min. The largest increase occurred at the left posterior heel while the smallest increase occurred at the right fifth metatarsal. The results show that plantar pressures increase with walking cadence.

[65] Quantitative Analysis of Cane Cadence with a Portable Microprocessor-Based System

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Sponsor: VA Rehabilitation Research and Development Service (Project #A624-RA)

Purpose—The purpose of this study was to define the effect of cane use on walking cadence. When studying plantar pressure, it is recommended to control cadence because the velocity of walking (stride length \times cadence) affects ground reaction forces.

Methodology—A quantitative definition of cadence with cane use was derived from 24 nondisabled subjects. Cadence data were recorded using a portable, microprocessor-based plantar pressure data-acquisition system at a sampling frequency of 20 Hz. The time of heel strike was recorded via a pressure sensor taped to the interior heel of the right shoe of each subject. Cadence was calculated from the number of steps per unit time. Data during

contralateral cane use, ipsilateral cane use, and normal gait were recorded for 4 minutes.

Results—Normal walking cadence without a cane was 109 steps/min. Both contralateral and ipsilateral cane cadences were significantly different ($p < 0.05$) than normal cadence. Cadence with use of the cane contralateral to the unloaded foot was 78 steps/min ($p < 0.05$). Cadence with use of the cane ipsilateral was 84 steps/min ($p < 0.05$). The difference between ipsilateral and contralateral cane gait was marginally significant ($p < 0.1$). This study showed that cane use significantly affects cadence, suggesting that the effect of a cane on cadence needs to be addressed when analyzing plantar unloading due to cane use.

[66] Plantar Pressures in Total Contact Casts

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Sponsor: VA Rehabilitation Research and Development Service (Project #A383-RA)

Purpose—The purpose of this project is to evaluate the effects of total contact casts on plantar pressures from nondisabled subjects.

Methodology—Total contact casting is used to aid in the healing of plantar neurotrophic ulcerations. The purpose of this study was to quantify the

effectiveness of total contact casting in reducing plantar pressures. Six able-bodied males (age 25–35) were studied. Plantar pressures were measured by taping eight pressure transducers of 0.5-mm thickness and 11-mm diameter over the first, second, fourth, and fifth metatarsal heads, medial and lateral midfoot, heel, and great toe of left foot. To

eliminate the effect of cadence on plantar pressures, the cadence with a cast was determined. Plantar pressures during walking with the cast and normal walking (but at cast cadence) were analyzed for 150 steps.

Results—The results showed an average decrease of 32.4% (4.7–49.4%) in plantar pressures under the

fifth metatarsal in all subjects when walking with the cast. In 5/6 subjects, the first metatarsal and great toe were unloaded by an average of 68.6% (37.8–84%) and 77.0% (54.8–87.4%) respectively. In 4/6 subjects the medial midfoot was not loaded without the cast, but was loaded 59–195 kPa with the cast. In 3/6 subjects, there was an increase in loading under lateral midfoot.

[67] Plantar Pressures Under Diabetic Insensate Feet

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Sponsor: VA Rehabilitation Research and Development Service (Project #A383-RA)

Purpose—The purpose of this project is to study the in-shoe plantar pressures from diabetic insensate subjects and nondisabled subjects.

Methodology—The purpose of this project was to study the variability of plantar pressures under insensate feet over time. Three diabetic insensate subjects were studied. Their feet were free from ulcers and trauma. Plantar pressures under seven locations of each foot were recorded during 4 minutes of continuous walking with a total of 45 tests (each test consisting of 6 trials) over a 2-year period (total 11,500 steps). The subjects walked on a 32-m walkway at their free cadences (mean 105 steps/min) with and without the assistance of a metronome respectively. An unpaired *t*-test

($p = 0.05$) was used for data analysis.

Results—Mean peak pressures ranged from 110 to 824 kPa, while mean pressure-time integrals ranged from 20 to 98 kPasec. The maximum within-subject standard deviation is 368 kPa for peak pressure and 48 kPasec for pressure-time integral. The average inter-trial consistencies were found to be 82%, 85%, and 74% in terms of pressure-time integrals, foot-to-floor contact durations, and peak pressures respectively. Pressure-time integral analysis showed inter-test consistencies in 50% of sensor sites. There were no significant differences in inter-trial pressure consistencies between uncontrolled and controlled cadences.

[68] Rehabilitation Strategies to Improve Symmetrical Force Production in Stroke Patients

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Sponsor: VA Rehabilitation Research and Development Service (Core Funds)

Purpose—The purpose of this study is to investigate the feasibility of a new rehabilitation strategy for improving symmetrical lower extremity force production in hemiplegic stroke patients.

Hemiplegia is a major consequence of stroke that contributes to significant movement dysfunction. One primary goal of rehabilitation is to restore

symmetrical control over force production output and timing in the lower extremities. Rehabilitation of bilateral, lower extremity function in hemiplegic persons will result in improved daily function for many activities (i.e., standing, walking, and stair climbing). Currently there are few, if any, rehabilitation approaches that utilize biomechanical princi-

ples of movement control as a basis for providing feedback of performance to both the clinician and patient. Application of our current understanding of neuromuscular control of bilateral, cyclical movements, such as pedaling an ergometer, should result in improved methods for training hemiplegic persons to regain efficiently lower extremity function.

The long-range goal is to improve lower extremity function in hemiplegic persons. We believe that this can be accomplished by training them to pedal an ergometer more symmetrically. The short-term objectives in this pilot project include identifying pedaling asymmetries in hemiplegic persons and then demonstrating improvement of symmetrical pedaling performance.

Methodology—Within the next one-year period, we propose to use existing experimental and computer modeling methods developed in our laboratory. Twelve hemiplegic subjects and 12 age-matched, neurologically normal subjects will pedal an ergometer modified to provide added comfort and safety. Pedal reaction forces will be measured by dual strain gauge transducers mounted in each pedal. Comparisons of pedal force variables (i.e., maximum peak force amplitude and phase, and

single limb work output) will be made between both lower extremities and between the hemiplegic and nondisabled subjects.

After the pedal force asymmetries have been characterized, the hemiplegic subjects will undergo one of two training protocols designed to demonstrate improvement in symmetrical force production. The control group will train by pedaling an ergometer without feedback of performance over 24 training sessions. The treatment group will pedal while receiving visual feedback on a selected pedal force symmetry measure over the same number of training sessions. Improvement will be evaluated by comparing baseline measurement of pedaling variables with measurements taken after the completion of the treatment regimen. In addition, the outcome of visual feedback treatment will be compared to outcomes measured in the control group.

Future Plans—Upon completion of these pilot studies, we intend to pursue further studies investigating the role of symmetrical force production in improving lower extremity function in stroke patients and evaluating the carryover of cycling exercises to more functional motor tasks such as walking.

[69] A Pilot Study of Handrail and Grab Bar Height to Reduce Falls by the Elderly

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Sponsor: *VA Rehabilitation Research and Development Center (Core Funds)*

Purpose—The objective of this pilot study is to evaluate a methodology for exploring the influence of the height of handrails on ramps and level walkways for fall prevention. Apart from deaths caused by motor vehicles, falling is the second largest cause of accidental death in all age groups. Of these deaths, two-thirds of the victims are age 65 or older. More than 12 million people require medical attention after accidental falls every year. There is a consensus in the literature that handrails reduce the incidence and severity of accidents.

For the elderly, the absence of a (stair) handrail is perceived as especially hazardous. The height from the floor at which rails are set probably

determines whether they can be grabbed, how quickly they can be grabbed, whether people can retain their grip, and whether their use can abort falls. Extant codes and standards show little agreement. Most national building and fire codes require rails to be set at 30 to 34 inches, or 33 to 36 inches. A recent Canadian study suggests that these heights are much too low.

Progress—The pilot study will indicate whether rail height is a significant variable, and whether the proposed methodology can be applied and developed for use in a more comprehensive study. Future studies will include stairs with a range of riser/tread

geometries, ramps of various gradients, and grab bars set above level floors.

Methodology—The subjects walked on a level surface. They were induced to lose their balance by mechanical means in the floor. The success or failure of the subject in grabbing rails set at various heights was recorded, as well as the reaction time taken for a successful grab; and finally, the forces of the grab responses under the condition of rail use and nonuse during ambulation were measured.

A level walkway with floor segments resting (invisibly) on steel skate wheels was constructed. When a walking subject puts a foot down onto a predetermined place on the floor, the floor segments slide forward or backward. The subjects, in effect, slip on the floor. The height of the experimental handrail is adjustable so that it can be set at seven different heights within the range from 30 to 42 inches. The rail is connected to load cells which

provide data on the loads exerted on the rail, and the direction of the load.

An electronic trigger activated by the movement of the walkway also starts a timer in a computer, activating a software program. When sensors detect movement in the rail consistent with a grab, the timer stops. This provides a measure of the reaction time in terms of the time taken to grab the rail. If the subject is already using the rail, the timer provides information on reaction time in terms of the time taken to exert a stabilizing force. A further measure is the success or failure of the grab. The subjects wear a parachute harness that is suspended from an overhead rail. This system prevents a fall from being completed by holding the subject upright after loss of balance.

Results—Twenty subjects were used for this pilot study, and the data analysis is underway.

[70] Electrical Stimulation Strategy to Inhibit Spasticity During Gait

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Sponsor: *Easter Seal Research Institute of Ontario*

Purpose—Spasticity can be defined in terms of its characteristics, the most salient of which is an exaggerated stretch reflex. Previous work has shown that it is possible to inhibit the stretch reflex of triceps surae by electrically stimulating the antagonist tibialis anterior muscle. With recent evidence suggesting the influence of the monosynaptic stretch reflex during gait, the aim of this project is to modify spastic gait by inhibiting the stretch reflex.

The project can be divided into two parts, each with its own specific goal. These goals are: 1) to determine the relationship between latency of stimulation, number of pulses in one stimulus burst, pulse frequency, pulse amplitude, and amount of inhibition; and, 2) assuming that the stretch reflex of the triceps surae influences gait, to develop a stimulation strategy during gait which would modulate triceps surae tone.

Methodology—The study involved able-bodied subjects and subjects with mild spastic cerebral palsy.

For the first part of the study, subjects are seated in the Ankle Actuating Device, a computer-controlled device which can impose rotary movements about the ankle joint, and hence cause a passive stretch of triceps surae. The tibialis anterior is stimulated to inhibit the stretch reflex of triceps surae. Exploratory experiments are performed to determine the relationship between the number of pulses, the stimulation frequency, the pulse amplitude, the latency and the amount of observed inhibition. These results allow the determination of the electrical stimulus parameters that are efficacious in inhibiting the stretch reflex for use in the second part of the project.

During gait, stimulation is timed relative to depression of a footswitch placed on the bottom of a subject's foot. Exploratory experiments are performed to determine the optimal latency relative to the footswitch depression for each subject. Using the VICON 3-D motion analysis and electromyographic (EMG) systems in the laboratory,

an assessment of each subject's gait with and without stimulation will be made.

Progress/Preliminary Results—The first part of this project has been completed and the gait studies are underway. For normal subjects, inhibition appears to increase with greater tibialis anterior twitch. Accordingly, inhibition increased with amplitude

and sometimes with number of pulses and frequency. Stimulation beginning at latencies of 140–250 ms before the onset of stretch appeared to yield the greatest inhibition.

For subjects with spasticity, lower stimulation amplitudes seem to be more effective. For one subject with spasticity, stimulation at higher amplitudes resulted in disinhibition.

[71] Biomechanical and Metabolic Study of Gait in Congenital Below-Knee Amputees: A Comparison of the SACH Foot and the Seattle Foot

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Purpose—The purpose of this study was to determine whether the energy-conserving design of the Seattle Foot permits more normal gait kinematics, dynamics, and energetics compared to the conventional SACH Foot in congenital, unilateral, below-knee amputees walking at their preferred speed.

Specific goals were: 1) to compare the energy cost of walking when wearing the SACH or Seattle Foot; 2) to quantify the mechanical advantages of the energy-returning characteristics of the Seattle Foot in terms of the work done in gait; and, 3) to investigate the compensation strategies used by amputees when walking with prosthetic feet.

Methodology—Assessments have been performed on eight subjects who: 1) had congenital, unilateral below-knee amputations; 2) were between 10 and 19 years of age; 3) had a foot length greater than 22 cm; and, 4) were successfully fitted with a PTB-type prosthetic socket.

Each subject underwent separate biomechanical and metabolic gait assessments using each of the two types of prosthetic foot. The biomechanical analysis consisted of 10 walking trials, during which lower-limb segmental movements were recorded in 3-dimensional (3-D) space using the VICON motion tracking system. Footswitches measured the timing of foot-floor contact, and ground reaction forces were recorded in 3-D using a Kistler force platform built into the gait walkway. Body segment anthropometric data were combined with the 3-D kinematic and ground reaction force data in an

inverse dynamics analysis to determine net moments and powers around the hip, knee, and ankle joints through the gait cycle.

The metabolic assessments were performed at Variety Village. Subjects walked for 8 minutes at self-selected speeds on an oval-shaped track while connected to a Beckman metabolic cart, through which were monitored certain physiological functions. Heart rate was recorded with a standard 3-lead ECG configuration. Oxygen consumption, carbon dioxide production and respiratory exchange ratio were recorded at 30-second intervals for the calculation of energy cost of walking, normalized to body weight, and walking velocity.

Results—Preliminary analysis of the biomechanical gait data has revealed that there are very small differences in the work and power profiles between the two types of feet at self-selected speeds of walking. Since neither foot is able to actively plantarflex against the weight of the body, the deforming foot (Seattle) can only regain its resting shape when weight is removed from it by flexion of the knee and hip joints at the end of the stance phase. In this regard, the work done by the hip flexors during the pull-off phase is slightly less when using the Seattle Foot. This small difference is not reflected in the metabolic data. There is no apparent energy cost benefit to using the Seattle Foot at the walking speeds chosen by these subjects.

When the subjects were separated into two groups according to their side of amputation, those

with right-sided amputations demonstrated significantly lower energy costs than those with left-sided amputations. Review of kinematic data may provide some insight into this effect; for instance, regardless of side of amputation, swing phase symmetry was

biased to the right side. This indicates that the right side swing phase was prolonged relative to swing time on the left, and reflects different roles for the right and left lower limbs in stance.

[72] Feasibility of Improvement in the Dynamics of Crutch Walking

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Purpose—This project was instigated by the following reasons: 1) the principal investigator previously worked on the development of a stowable crutch—which is now commercially available—and became interested in crutch design; 2) the standard axilla crutch has been used for 5,000 years and has not changed significantly; and, 3) the majority of people with paraplegia opt for wheelchair mobility rather than crutch ambulation.

The goal of the project was to look at alternative crutch designs to assess whether any of them offer improvement in the high energy cost of crutch gait to make them a more feasible option to the use of wheelchairs.

Methodology—Four different crutch designs were tested with five disabled people who are regular users of crutches and with five nondisabled people who were tested with free knees and with rigid knees to simulate knee-ankle-foot orthoses with locked knees. All subjects were tested in the Children's Hospital at Stanford Motion Analysis Laboratory by calculating the Energy Expenditure Index

(*walking heart rate minus resting heart rate divided by average velocity*). The Student's *t*-test was used to determine the significance of findings.

Results—Data from testing the four crutch designs compared to standard crutches show that there are no major, significant improvements. Even though the four crutches offer innovative ideas and potential for improvement, the measured energy expenditures with regular crutch users show only minor differences compared with the standard axilla or forearm designs.

Implications—Based on the results, the roller/rocker crutch, the prosthetic foot crutch, and the spring/pogo crutch do not appear to offer improvement in the dynamics of crutch walking and do appear to offer some disadvantages in the practicality of use. Even though the saddle/suspension crutch showed no major improvement in energy expenditure, it did show some promise that appears to merit additional pursuit of the concept.

[73] Quantification and Display of Musculoskeletal Anatomy

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—Patient-specific anatomical data, in a form suitable for mathematical processing, are essential for accurate determination of the mass and inertial properties used in Newton's equation to

calculate forces from accelerations, for specializing mathematically expressed, generalized musculoskeletal models to the particular patient's anatomy, and to provide the surgeon, via computer graphic

displays, with realistic and accurate visual information describing the patient's anatomy.

Progress—We have demonstrated the feasibility and practicability of applying computer tomography (CT) or magnetic resonance imaging (MRI) data to automatically calculate the mass, mass center, and inertial tensor of body segments with X-ray tomography. The CT number defines local tissue density and is converted to mass density for inertial properties and to gray scale to compute visualization displays. MRI image data requires contouring regions of different density (i.e., bone, muscle, etc.), and assigning tissue density values. We have developed software algorithms to automatically extract from CT and MRI data, and store efficiently in computer memory, the geometrical information necessary to generate colorgraphic computer displays of aspects of a patient's anatomy (i.e., the skeletal bones, joints, muscles, muscle insertions and origins, and ligament insertions and origins, etc.).

Using such displays, we have demonstrated the ability to perform any conceivable intertrochanteric osteotomy using a three-dimensional (3-D) computer display of a patient's femur, described from actual CT data. Our approach is fundamentally different from that of commercial firms developing similar anatomical display capability (CEMAX, PIXAR, SIEMENS) in that we are interested in "doing surgery" on the display (i.e., "cutting" bones and "glueing" them back together). Commercial firms are content to display the intact anatomy as is. Our

approach makes very different demands on the organization and display of the data-base representing the anatomical information. For 3-D display and graphic manipulation of anatomical material, we are employing both the more common "pixel" approach (using a Silicon Graphics Personal IRIS 4D20) and a volumetric "voxel" method (on a Sun 4/280S system equipped with Sun/TRANCEPT image generator). The two methods are complementary. The surface representation method allows fast manipulation of the anatomy, but requires considerable preparation of the contours. The volumetric method requires little preprocessing, but is computationally expensive and requires specialized image processing hardware. The volumetric representation is clearly superior for computation of mass/inertial properties of patient-specific body segments. The volumetric displays are particularly striking graphically and effective interactively. Starting with the external appearance of the body, software (using tissue density as control), can "strip off" the skin, then the subcutaneous tissue, followed by muscle, leaving the skeletal structure.

CT-based images of bone suggest higher densities at ligament and tendon insertion sites; thus, noninvasive patient-specific determination of this data for musculoskeletal modelling appears feasible.

Recent Publications Resulting from This Research

Determination of Body Segment Parameters in Conjunction with Computer-Aided Surgical Simulation. Brown GA, Rowell D, Mann RW, East/West Coast Gait Laboratories Conference, San Diego, 1990.

[74] Mobility Analysis

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—Quantitative functional assessment of neuromusculoskeletal disorders mandates an ability to acquire precise, accurate, and high data-samples of the kinematics and dynamics of the affected person. Such measurement is imperative to confident evaluation of the individual's movement patterns before and after interventions such as surgery, physical therapy, and application of internal and

external prostheses and orthoses. A major effort of the Harvard-MIT REC has been dedicated to what is now recognized as the premier movement analysis extant.

The MIT TRACK® (Telemetered Rapid Acquisition and Computation of Kinematics) software complements Selspot or other electro-optical or video cameras to process human movement data.

The NEWTON program uses this kinematic data together with forceplate data and body-segment inertial properties to estimate the net forces and moments across the skeletal joints. Unlike other gait analysis systems which place markers on the skin over the putative joint "centers," TRACK is based on segmental analysis treating each body segment (i.e., foot, shank, thigh, pelvis), as a separate entity free to move in 3-dimensional space. Arrays of markers located on each segment permit acquiring and following the six to record the 6-degrees-of-freedom of each segment (3 translations and 3 rotations).

Other features of TRACK are:

- A normal and natural milieu for the human subject, minimizing artificial aspects of the experimental environment and the burden on the subject.
- High precision, three-dimensional kinematic data, with body-segment translations and rotations relative to a laboratory fixed frame of reference, at high data rates relative to the frequency components of human movement, in a form suitable for subsequent dynamic analyses.
- Automaticity—no human intervention in data acquisition and quantization to eliminate human subjectivity and error and to reduce drudgery.
- Real-time processing of kinematic and forceplate data to provide access to kinematic and dynamic results during or immediately after movement.

Progress—The TRACK system is operational at MIT and MGH, at Boston University's NeuroMuscular Center, and at the University of Bologna. Originally coded in FORTRAN and running under VMS on a DEC PDP 11/60, TRACK has been reprogrammed in the "C" language and transferred to a Sun 3 Microcomputer System running in UNIX. TRACK data is now available at over 100 Hz for real-time control of experiments requiring movement input. For observational and comparative purposes, TRACK output is displayed as animated limb and body segments, each a 4-color 6-sided solid assembled into a representation of a person. This visual display, together with graphical information, is presented on a Silicon Graphics Personal IRIS (4D20) at 20 Hz. A version coded for personal computers is offered commercially by

OsteoKinetics, Inc., Newton, MA, under copyright license from MIT.

The kinematic quality of TRACK output has inspired careful study of optimal post-processing of the sampled position data to faithfully retain all movement—significant frequencies while producing trajectory smoothness essential to satisfactory differentiation. Velocity data is necessary for instant helical axis determination to present joint axis trajectories as axode in order to compare kinematic data independent of subject direction of movement and frame of reference. Acceleration data is necessary for dynamic estimates. Even higher order derivatives are necessary to apply differential geometry analyses to quantitatively compare axode trajectories.

Our study of optimal post-processing has clearly demonstrated the advantage of smoothing over filtering. We have now compared position data acquired with TRACK arrays mounted noninvasively on the skin on body segments with comparable arrays mounted on bone pins into the skeleton *in vivo*. These, in turn, have been compared with the usual practice of other gait laboratories, that of mounting "joint center" markers on the skin over bony prominences at each of the lower extremities.

With fixed position cameras, the viewing volume for accurate data is about 2m on the side or one gait cycle. To study stride-by-stride variability and other noncyclical and wider ranging movement patterns, we have developed Large Volume TRACK. The fixed cameras now observe the subject via computer-controlled mirror systems which rotate to keep the LED array images aligned to the camera optical axes as the subject moves throughout a much larger viewing volume.

Advancing Large Volume TRACK required developing improved calibration means, both for correcting inherent nonlinearities in the camera lens and electro-optical transducers, and in relating the positions and orientations of the cameras to each other and to the laboratory frame. The internal camera calibration technique we have developed and demonstrated fully exploits the 12-bit digitization of the analog output of the lateral-effect diodes in the electro-optical cameras. The new external calibration system is clearly superior to both our prior technique of mounting the cameras on an optical bench and to the widely used Direct Linear Transform

(DLT) space-frame approach. We use LEDs mounted on a simple planar frame, rotated about a vertical axis by a stepping-motor, so that the plane can first face one camera, sweep out a volume, and then be rotated to face the other. Eliminating the DLT space frame avoids difficult reflections from frame structure between an LED and the camera, yet rotation of the plane simulates a volume. Finally, a new calibration algorithm has been developed which does not require that both cameras simultaneously see the same LED.

Recent Publications Resulting from This Research

Real-Time Analysis and Display of Kinematic Data. Lord PJ, Mann RW, East/West Coast Gait Laboratories Conference, San Diego, 1990.

Segmental Analysis in Kinesiological Measurements. Ladin Z et al., in Proceedings of the First World Congress of Biomechanics, La Jolla, CA, 1990.

A Technique for Large Volume Acquisition of Human Kinematics. Mansfield PK, Mann RW, East/West Coast Gait Laboratories Conference, San Diego, 1990.

Telemetered Rapid Acquisition and Computation of Kinematics: The M.I.T. TRACK Movement Analysis System. Mann RW, East/West Coast Gait Laboratories Conference, San Diego, 1990.

TRACK[®]: The MIT Movement Analysis System Which Combines Opto-Electronics, LED Arrays, and Software to Produce Rapid, Automatic, and Precise 3-D Position and Orientation Kinematics and Dynamics. Rowell D, Mann RW, in Proceedings of the International Symposium on Gait Analysis State-of-the-Art of Measuring Systems and Their Importance in Prosthetic and Orthotic Technology, Berlin, 1990.

A Large Volume Close-Range Photogrammetric System. Mansfield PK, PhD diss. Massachusetts Institute of Technology, 1990.

[75] Musculoskeletal Modelling

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Sponsor: National Institute on Disability and Rehabilitation Research

Purpose—Musculoskeletal modelling has been a focus in our research for over a decade. The accurate kinematics from TRACK and dynamic calculations using NEWTON make feasible the estimation of the time course and net force levels in each of the redundant set of participating muscles producing a movement pattern. However, to make such models subject-specific, the mathematically expressed models which define the three-dimensional geometry of the skeleton, joints, muscles, and ligaments of the human lower extremity must be adjusted to the parameters specific to the patient (i.e., bone length dimensions, and muscle/tendon origins and insertions). Our computer tomography and magnetic resonance imaging data approach produces the information necessary for such individualization of our musculoskeletal models.

Progress—The data from the pressure-instrumented prostheses, and corroborating evidence from Newman Laboratory amputation prostheses research, and the posture and balance studies at the Massachusetts General Hospital's Biomotion Laboratory, have made increasingly clear the ubiquity and significance of agonist-antagonist muscle activ-

ity (co-contraction) in virtually all postural adjustments and movements. The significance of these findings to gait analysis, the estimation of joint forces and moments, muscular skeletal modelling, and individual muscle force determination using optimization approaches, cannot be underestimated. In a word, all extant studies of the above have been based on, or have yielded, the lower limit of the forces the muscles provide and the joints experience. Since all such studies start with movement data (i.e., kinematics), they reflect only the net muscle forces which cause the motion, due to the muscle moment at the joint. In co-contraction, muscles opposed (antagonistic) exert balanced forces, and therefore, joint forces, above these net values: but these balance forces do not contribute to the observed motion.

Results/Implications—Amputation prosthesis research in our laboratory is showing that co-contraction is essential to the control of the impedance or stiffness of the joint, especially when the human interacts with the environment, as in the use of tools.

We are developing a new analysis technique to include co-contraction in our optimization analyses which estimate the force-time output of the individual muscles. In such studies, a cost or penalty function (e.g., energy expenditure), is minimized to find those solutions which also satisfy the dynamic constraint equations. Adding a new "stability" cost function requires that the muscle forces, and their aggregate, the joint forces, be adequate to keep the body stable during movement maneuvers.

Recent Publications Resulting from This Research

- Agonist-Antagonist Muscle Co-Contraction: Ubiquitous But Unappreciated. Mann RW, in Proceedings of the 13th Annual RESNA Conference, Washington, DC, 57-58, 1990.
- A 3-D In Vivo Knee Model: Relationships Between Geometry, Dynamics, and Kinematics. Fijan RS, Mann RW, ASME Winter Annual Meeting, Symposium on Issues in Modeling and Control of Biomechanical Systems, Dallas, 1990.
- A Three-Dimensional Mathematical Model of the Human Knee Joint. Fijan RS, PhD diss., Massachusetts Institute of Technology, 1990.

[76] Development of an In-Shoe Pressure Measurement System

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Sponsor: *Scottish Home and Health Department*

Purpose—Our purpose was to develop an in-shoe pressure measurement system based upon arrays of piezoelectric polymer film sensors strategically positioned in a series of semi-matrix standard insoles. This work can be sectioned into three phases: 1) to develop a 4×4 matrix array transducer; 2) to develop a set of standard insoles incorporating a minimum number of sensor elements; and, 3) to perform comprehensive clinical measurements with the new system together with a dynamic pedobarograph.

Progress/Methodology—Preliminary research had previously been undertaken and an in-shoe pressure measurement system designed around positionable discrete piezo film transducers had been developed. Copolymer piezo film has been incorporated into individual transducer configurations that have been fully investigated and are calibratable to within 10% uncertainty. For each foot, eight of these transducers provide pressure data for multiple footsteps for particular anatomical sites of interest. However, to avoid having to construct an insole for each subject, an insole with a matrix array of sensors is desirable. Most of the progress in this pilot year has been in the area of transducer development.

Similar technology has been used to develop a small 4×4 matrix array transducer of sensors, each measuring 5 mm in diameter. PVdF piezo film has been used rather than copolymer film because of its cost and dimensional advantages. There still remain

some constructional challenges that are primarily related to spherical bending problems. Erroneous data can be produced if piezo film is stretched or bent, and so individual stiffening elements are used for each sensor site. Unfortunately, unless the flexible layer upon which these elements are mounted has spherical bending properties such as rubber, then the whole configuration tends to have a chainmail-type flexibility. Thus, delamination of the construction is a resulting problem.

The charge signals produced by each sensor (of the order of 20pC/N applied force) are processed using charge amplification techniques. It is desirable to multiplex these front-end signals in order to simplify the electronics, and several novel prototype circuits have been investigated. The output from this circuitry is then supplied to an A/D data acquisition card which is plugged into an IBM PC. Custom software has been developed to acquire the stream of data from the electronics and also to control this electronic system.

Future Plans—Initially, extensive tests are to be carried out upon the 4×4 matrix transducer array. In conjunction with a dynamic pedobarograph, clinical measurements will be carried out upon three patient groups: normals, those with anatomical abnormalities (such as rheumatoid arthritis), and those with neuropathic disorders such as diabetes. Performance difficulties with the transducer will thus be highlighted and tackled before concentrating

efforts upon the development of a set of standard semi-matrix insoles.

The sensors for these final insoles will cover only part of the area; pressure distribution information will be obtained for limited areas of the plantar surface of the foot. Careful consideration will therefore have to be given to how these sensors are distributed. It is thought that a maximum of 100 sensors will provide adequate information for a men's size 12 insole; however, this requirement will

have to be determined after comparative measurements have been taken using the dynamic pedobarograph.

Work will also be carried out to further develop the electronic system, which will essentially be an upgrading process. Further software development will be necessary so that the data from the sensors is acquired at an adequate rate, and can be displayed, manipulated, and analyzed.

[77] Computer-Based Referral Program for Temporomandibular Joint Dysfunction

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Sponsor: None listed

Purpose—A computer-based referral program has been developed to assist general practitioners in the recognition of temporomandibular joint dysfunction. The program indicates whether or not a patient should be referred to a specialist center, and is not intended to suggest treatment regimes.

Progress/Methodology—The program is not a complete diagnosis and treatment, but has been designed to lead the clinician through the relevant questions that should be asked, and indicates whether or not the patient should be referred to a specialist center for further investigation. The user is first required to enter the patient's personal details, and the program then prompts for presenting symptoms, medical

history, other symptoms such as stress, etc., until it is able to make a decision regarding referral. A charting of the dentition is included, and the program will provide both a hard copy of the data and a suitable referral letter.

The system is available in Basic software for both BBC and IBM microcomputers.

Preliminary Results/Future Plans—The initial program has proven useful not only in general dental practice, but also in the teaching of temporomandibular joint dysfunction, as described in last year's report. Work is planned to extend the program to include diagnosis and treatment.

C. Other

[78] Mathematical Modeling of Intervertebral Disc Prolapse

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Sponsor: VA Rehabilitation Research and Development Service (Core Funds)

Purpose—It has been well documented that flexion of the spine combined with sudden loading is a

major cause of disc prolapse. The purpose of this project is to determine mathematically the mechani-

cal factors involved in disc prolapse. It is planned to build a comprehensive mathematical model of a lumbar motion segment and then use this model to study: 1) the effect of sudden as well as gradual loads; 2) the effect of changing properties of the annulus and the nucleus to simulate degeneration and aging; 3) the effect of nuclear geometry on stresses in the annulus; 4) the effect of partial fissures on stresses in the annulus; and, 5) the circumstances leading to disc prolapse.

Methodology—There have been few attempts to model the intervertebral disc. Most model the disc alone and do not take into account the effect of other soft tissue or the adjoining bone. Models for a 2-vertebra construct do take into account other soft tissues; however, they fail to model the intervertebral disc comprehensively.

In this model, the finite element method will be used in conjunction with a stiffness method to build the model. Mechanical properties of the various elements will be obtained from the literature as well as from mechanical tests to be conducted at Emory University as a part of another project. The elements to be considered are the intervertebral disc with its adjoining vertebrae, and all the soft tissue connecting the vertebrae. The vertebrae will consist of cancellous as well as cortical bone. Soft tissue will

be all ligaments, cartilaginous endplates, and articular facets. In addition, all properties will be considered to be time-dependent.

Ligaments will be modeled as elements that can sustain tensile load alone. The ligaments to be considered are: the interspinous ligament that joins the tips of the spinous processes, the intertransverse ligaments that join the tips of the transverse processes, the anterior longitudinal, the posterior longitudinal and the supraspinous ligaments, and the ligamentum flavum. Vertebral bodies consist mainly of cancellous bone with cortical bone at their periphery, and the different properties of each will be used in these regions.

The most important component of the model is the intervertebral disc. The annulus will be modeled as a composite with collagen fibers lying within a matrix. The collagen fibers will follow the orientations that are seen in reality and thus will consist of a ply or laminated structure. The nucleus pulposus is generally considered to be an incompressible fluid whose properties were given by Yang and Kish in the Proceedings of the Twelfth Annual Meeting of the American Society for Biomechanics in 1988.

Progress—The work on this project has just begun. We are still in the stage of narrowing all the parameters to be studied.

[79] Biomechanical Measurement of Swallowing for Assessment, Diagnosis, and Biofeedback Therapy for Treating Dysphagia

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Sponsor: *Edwin Shaw Hospital Foundation*

Purpose—Dysphagia presents a major problem in the comprehensive rehabilitation of patients with stroke and other head injuries. Dysphagia often leads to several clinical problems such as aspiration, dehydration, and inadequate nutrition. Identification and treatment of the patient at-risk of aspiration is important from a clinical standpoint. The swallowing process can be divided into three distinctive phases: oral, pharyngeal, and esophageal phase. We have developed procedures for quantitative assessment and diagnosis of dysphagia involving the

oral and pharyngeal phases. We are developing methods for biofeedback therapy using these measurements.

Progress/Methodology—We have identified and developed techniques to measure several biomechanical parameters which aid in the quantitative assessment of the oral musculature in dysphagia. These parameters include: 1) lip closure pressure; 2) lip interface shear force; 3) tongue thrust in forward, backward, and the two lateral directions; and,

4) swallow pressure. We have found statistically significant differences in the above parameters measured in normal and dysphagia patients.

For the quantification of the pharyngeal phase, two ultra-miniature accelerometers were placed on the outside of the throat. In addition, the swallow pressure was monitored with a catheter placed at the base of the tongue and connected to a pressure transducer. Normal subjects and dysphagic patients were measured for acceleration and swallow pressure simultaneously.

Swallowing in normal individuals gave rise to a characteristic acceleration pattern which could be well reproduced. The amplitude of acceleration varied from 1 to 2 g. There was no time lag between the appearance of the pressure wave and the appearance of the acceleration wave characteristic of swallowing.

By contrast, the characteristic acceleration pattern was either absent or significantly delayed. The amplitude of acceleration varied from 0 to 0.5 g. In those patients who could trigger a swallow, we found significant lag times between the acceleration and pressure waveforms. Additionally, we measured the biomechanical parameters upon admission, and after three weeks of thermal exercise therapy in several patients. We found significant improvements in the acceleration amplitude and pattern after the 3-week therapy. We found similar improvements in

oral biomechanical parameters (tongue thrust, lip pressure, etc.) after 3 weeks of oromotor exercises.

We have developed portable, easy to operate audiovisual devices for biofeedback training of patients with oral dysphagia. The visual feedback is in the form of an LED bar graph display with an increasing number of lighted LEDs and increasing force on the force-measuring transducer. The audio feedback system provides a fixed tone of varying intensity.

Results/Implications—Results have demonstrated the clinical acceptability of the biofeedback devices. Studies are being conducted to evaluate the efficacy of biofeedback therapy, using three groups of patients with oral dysphagia. Results also suggest that the biofeedback therapy can enhance recovery rates in oral dysphagic patients, and can augment current therapeutic techniques.

Publications Resulting from This Research

Biomechanical Measurements to Characterize the Oral Phase of the Dysphagia Patient. Reddy NP et al., *IEEE Trans Biomed Eng* 37:392-397, 1990.

Clinical Correlation of the Biomechanical Measurements of the Dysphagic Patient. Canilang EP et al., *American Congress of Rehabilitation Medicine Conference*, Phoenix, AZ, 1990.

Noninvasive Acceleration Measurements to Characterize the Pharyngeal Phase of Swallowing. Reddy NP et al., *J Biomed Eng* 13:379-383, 1991.

[80] Kinematics and Kinetics of Upper Limbs

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Sponsor: *National Institutes of Health*

Purpose—Kinematic and kinetic studies of the human upper extremities have been one of the long-term tasks in the Biomechanics Laboratory at the Mayo Clinic. The goals of these studies are to understand the functional anatomy and define the capacity of the human body. The information is then used to better understand the possible mechanism of injury and cause of pathology to improve the modalities of surgical and therapeutic treatments.

Through the years, various analytic models have been developed based on the anatomic struc-

tures and material properties of the body for the studies of force transmission across the joints of the finger, thumb, wrist, elbow, and shoulder joints. Experimental procedures for the measurement of the associated kinematic and kinetic data have also been developed by using the technologies of electrogoniometers, magnetic tracking systems, video-based motion systems, force plates, and three-dimensional load transducers and sensors.

Progress—In the last year, kinematic and kinetics analyses of the upper extremity involving activities

such as push-up exercise, isometric and isokinetic training, as well as wheelchair propulsion were studied. The anatomic constraints and stability of the thumb and shoulder joints have been extensively examined. The kinematic comparison of a few selected implants for total elbow arthroplasty has also been performed.

Future Plans—Applications of these developed techniques and protocols to better understand the rehabilitation procedures currently used in clinic for

patients after injury and surgery is considered in the near future.

Recent Publications Resulting from This Research

Functional Ranges of Motion of the Wrist Joint. Ryu J et al., J Hand Surg 16:409-419, 1991.

Isometric and Isokinetic Endurance Testing of the Forearm Complex. Motzkin NE et al., Am J Sports Med 19:107-111, 1991.

Three-Dimensional Kinematics of Glenohumeral Elevation. An KN, et al., J Orthop Res 9:143-149, 1991.

Valgus Stability of the Elbow. Morrey BF, Tanaka S, An KN, Clin Orthop Rel Res 265:187-195, 1991.

[81] Role of Taper in Crown Retention

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Sponsor: None listed

Purpose—The purpose of this study has been to investigate the physical basis for an observed unusual effect in the retention of dental crowns. Prepared teeth are normally cut down to a particular taper, and the fitting surface of the prosthetic crown is similarly tapered to be a precise fit, with a thin cement layer holding the two together. Prior to the current study, it was generally thought that retention increased with decreasing taper so that maximum retention would be achieved with no taper at all. However, in practical terms, a parallel preparation is difficult, and dentistry has generally adopted a slight taper as being clinically achievable. This view has pervaded all dental practice, and has rarely been challenged. However, recent practical studies by one of the authors suggest that the previous work may be in error, and that maximum retention may in fact be obtained at a finite taper in the region of 7-15 degrees. The purpose of the current study is to seek a rational explanation for this observation, which might have applications in other medical situations such as retention of implants.

Progress—The tapered shapes of clinically prepared teeth are not axisymmetric; therefore, a proper analysis of their retentive capabilities is difficult. This can be illustrated in incisal teeth, which clearly cannot be cut down to axisymmetric forms. Instead, they are tapered front-to-back, may even change

angle along the taper, and present a complex three-dimensional stress problem.

In our study, we have followed the previous literature in simplifying the problem to an axisymmetric cone, and since the prepared teeth are never brought to a point, the conic model is assumed to be truncated. The practical work which stimulated our study was itself carried out on extracted human teeth cut down on a lathe to model truncated cones. In the study reported here, we have been considering the separate contributions of the flat top and tapered wall to the overall retention for a wide range of cones within the overall dimensions of normal human teeth.

Empirical attempts to deduce an equation relating these separate components to the observed retention have so far been unsuccessful. We are currently unable to explain why retention should be a maximum at some intermediate taper.

Methodology—The prior practical study with human teeth carried out by one of the authors involved cones of various sizes and tapers. As a preliminary study, we have taken this data and calculated both top and sidewall surface areas. These have been used together with the known taper angles and measured retention strengths in attempts to produce empirical mathematical models based on tensile failure of the top surface with tensile and/or shear failure of the

sidewall interface. Separately, software is currently being developed to allow computerized generation of the complete nests of cones of varying dimensions which would all fit within the human tooth.

Preliminary Results—No satisfactory explanation or

data correlation has been forthcoming, and it may be necessary to investigate more closely the exact mode of failure to assist with further mathematical modeling. Interestingly, one possibility being considered is that this work may be linked to the Morse retention taper used in fixed bits on lathe machines.

III. Functional Assessment

[82] C SCAT: A Method for Differential Diagnosis of Tremors Based on Their Response to Mechanical Loads

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Sponsor: *VA Rehabilitation Research and Development Service (Project #F482-RA); Burke Rehabilitation Center*

Purpose—This research and development project is meant to test the idea that more definitive distinctions can be made among types of pathological tremor by observing the variation of objective tremor characteristics with applied mechanical loads. This hypothesis is based on earlier work in this group and elsewhere, in which sensitivity, or stability of frequency-domain tremor descriptions to added masses, springs, and dampers were used as the basis for investigating tremor mechanism. C SCAT (Computer-based System for Clinical Assessment of Tremor) is meant as a prototype instrument for use by neurologists to diagnose movement disorders in a way which will offer more reliable prediction of the effect of drugs and obviate trial-and-error prescription.

Progress—The first C SCAT unit has been completed. It is a one-degree-of-freedom computer-controlled manipulandum based on a brushless DC motor digitally controlled to simulate variable amounts of added mass, damping, and elastic resistance. The entire device is mounted for clinical convenience on a cart which provides the necessary sturdy base and lockable casters. A system of adjustable fixtures, limb cuffs, and supports makes it possible to test the left or right arm of a patient in wrist extension/flexion, forearm supination/pronation, and elbow extension/flexion. C SCAT presents a simple tracking task via an arc of LEDs.

The clinician conducting the test interacts with it through a friendly interface based on a keyboard and menu displays. An extremely detailed database management system has been built-in to facilitate collection and study of expected experimental evaluation data.

During the past year of work, C SCAT was fully characterized in the lab and used for the first time with tremor patients at the Burke Rehabilitation Center. These tests revealed the need for several technical changes including a spectral analysis package with greater resolution and a load simulation program which controls impedance rather than admittance. The convenience of most of the adjustable features was verified.

Future Plans—Continued experimental evaluation at the Brockton/West Roxbury VA Medical Center will begin when technical changes are complete. Clinical reactions as well as objective data will be collected. The primary task will be to determine if our hypothesis is correct: that differences in tremor mechanism which determine drug response can be detected with a test protocol of practical length.

Recent Publications Resulting from This Research

Design of the Patient Interface for a Computer-Based Tremor Characterization System. Brongo D, Rosen MJ, in Proceedings of the 14th Annual RESNA Conference, Kansas City, MO, 128-130, 1991.

[83] Interactive Scientific Visualization of Human Movement Biodynamics

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Sponsor: VA Rehabilitation Research and Development Service (Core Funds)

Purpose—A high-dimensional space is usually required to fully describe the complexities of human movement. Accordingly, it is difficult to fully appreciate and understand relationships such as those between motion dynamics and physiological or biomechanical variables without scientific graphic visualization. During the past decade, several investigators have addressed this issue by developing computer graphics-based models. However, most of these models are limited: they provide a means of visualizing only specific sets of variables or only static displays. Much of the work on human movement has focused on creating realistic graphical depictions of articulated body segments. Our work differs from this in that it focuses more on providing users with a means of studying human movement through multiple two-dimensional (2-D) and three-dimensional (3-D) state spaces that may be customized to their needs. Our software allows these relationships to be explored easily by people with a minimum knowledge of computer programming.

Methodology—A package was implemented on a PC-based platform using an ATVista™ graphics co-processor (TrueVision, Inc.). A menu-driven, multiple-window, real-time environment was selected as the basis for the visualization package with the intent of imposing no constraints on the relationships that can be examined.

The software provides a means of defining 3-D and 2-D interactive windows. Three-dimensional windows may contain any dynamic or time-varying data which may be observed from any perspective. These data may include moving vector fields, body segments (rigid bodies or stick figures), or anatomical landmarks. For example, a 3-D window may consist of the measured ground reaction force vector superimposed on a vector that represents the computed trajectory of the whole-body center of gravity.

Two-dimensional windows may be used to examine time-varying relationships. These windows incorporate moving cursors that provide users with a means of visualizing relationships between 2-D and 3-D data. Users may move these cursors forward or backward through data with a variable rate. Two-

dimensional windows may also be rescaled or rearranged to highlight or remove specific features of the data.

The software also provides a means for visualizing the differences between two or more sets of data. For example, users may create displays to visualize differences between body segment motions predicted using a hypothetical model and actual motions or differences in body segment trajectories that result from different strategies for performing certain tasks.

The user may also spawn other applications that may be used to process data contained in any window. These data may be evaluated graphically and readjusted by spawning other applications. Thus, the software may be used as an integral part of a decision-making process for applications such as computer-aided design.

Progress—This software is currently used to study various aspects of the biodynamics of lifting. Current versions of this software are available for beta-testing.

Future Plans—Future plans include developing an inference engine that can be used to detect and study movement disorders by studying the spaces that knowledgeable clinicians use to analyze and understand movement disorders, adding elementary variable transformations and adding the capability of visualizing 3-D time-variant or time-invariant relationships.

Much of the work on human movement has focused on creating realistic graphical depictions of articulated body segments. Currently, we represent body segments as either stick figures or rigid 3-D segments. In order to remove this abstraction, we are developing a feature which will allow the clinician to 'play back' recorded video simultaneously with other data in real-time.

Recent Publications Resulting from This Research

An Interactive Tool for Visualizing the Biodynamics of Human Movement. Morris T, Trimble J, in Proceedings of the 14th Annual RESNA Conference, Kansas City, MO, 118-120, 1991.

[84] Functional Assessment of the Performance Capacity of the Wheelchair-User Combination

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Sponsor: *Innovative Research Programme/Aids for the Handicapped*

Purpose—A protocol for the functional evaluation of the wheelchair-user combination during the course of rehabilitation is being evaluated. The functional work capacity and performance of the wheelchair-user combination under daily conditions in a group of male spinal cord injured subjects are evaluated each month. The results of the tests are compared to the outcome of the rehabilitation process. Thus, the predictive value of the protocol with respect to the functional capacity of the wheelchair-user combination is assessed, the individual process of rehabilitation is evaluated continuously, and selection and provision of the wheelchair may be determined more accurately.

Methodology—Exercise tests will be performed on a stationary transportable wheelchair ergometer, and on a standardized wheelchair track. Heart rate and ECG will be monitored in conjunction with power output and energy cost. Both a sprint protocol and an aerobic maximum exercise test will be conducted on the ergometer at different stages in the rehabilitation process. The cardiorespiratory stress of several tasks on the wheelchair track will be evaluated similarly. A computer-controlled wheelchair

ergometer was developed in cooperation with Sopur wheelchair manufacturers. It allows standardized exercise testing in conjunction with the study of torque and power production.

Progress—Thirteen spinal cord injured subjects currently participate in the project and are assessed each month. Results of an evaluation of the cardiorespiratory strain of daily wheelchair use in 44 male spinal cord injured subjects who completed the rehabilitation program several years before are being published at this stage. Peak loads are quite common, whereas training of the cardiovascular system as a consequence of normal daily wheelchair use is absent.

Recent Publications Resulting from This Research

Cardiovascular Responses During Activities of Daily Life of Wheelchair Users with a Spinal Cord Injury. Jansen TWJ, et al., in Proceedings of ECART, Maastricht, 6.4, 1990.
Effect van Dagelijkse Levensverrichtingen op de Functionele Belasting van Rolstoelgebruikers met een Dwarslaesie. Janssen TWJ, Oers CAJM van, Woude LHV van der, *Bewegen en Hulpverlening*, 7:185-196, 1990 (Dutch).
La Tension Cardiovasculaire au Cours d'Activites Quotidiennes Chez un Groupe de Paraplegiques Masculines. Janssen TWJ, et al. (in press).

[85] ELITE: A 3-D Motion Analysis System

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Sponsor: *Italian Ministry for University and Scientific Research, Italian Research Council*

Purpose—The ELITE project is oriented to the continuous development of a fully automatic (but not cumbersome), system for motion analysis. The system is intended for use in clinical evaluation, diagnosis, therapy, and prostheses assessment. It is also used for basic research in neurosciences and orthopaedics.

Progress/Methodology—ELITE is based on optoelectronic noncontacting sensors (special video cameras). These sensors are based on solid state two-dimensional devices (CCD) scanned up to 100 times per second. They are electronically shuttered in order to allow use with fast movements and are coupled with a solid state infrared flash. The video

signal is processed in real-time by special-purpose hardware which implements a cross-correlation algorithm. A kernel is shifted onto the incoming image which is mapped to a cross-correlation output. The output image shows peaks in correspondence of marker-shaped objects in the input image. The markers are characterized as bright circular spots. They are obtained by using small plastic supports coated with retro-reflective paper. The size varies with the field of view (FOV) from less than 1 mm up to 1 cm for a FOV of 2.5 meters. For each marker, several pixels characterized by a high value of cross-correlation are found in the output image. They are sent together with their sensor coordinates to a general purpose personal computer (PC). Here, the center of mass of each marker is computed leading to a very high resolution ($>1/65,000$ of the FOV).

Also collected on the PC are other data, such as EMG and ground reactions from force platforms. Starting from these data, the software level provides for distortion correction, matching between coordinates of the markers and body landmarks (labeling), three-dimensional (3-D) coordinates reconstruction, derivative assessment, modeling, and results representation.

Labeling of the markers is a problem that always arises with passive markers. It has been solved by combining a dynamic trajectory tracking procedure with a knowledge-based model of the movement. Three-dimensional coordinates are computed by an iterative least-squares algorithm based on the linearization of collinearity equations. It leads to a 3-D accuracy of $1/3000$ of the FOV. Derivative assessment has been carried out by using

an AR signal modeling combined with FFT and finite impulse response filtering. Other processing includes force platform and EMG data analysis and body modeling. Recently, the analysis of body surfaces and body volumes with application in orthopaedics and respiratory physiopathology have been explored. Markers are placed on the surface which is subsequently modeled with splines curves. A laser scanner is under development for this purpose. In this case, the laser-beam reflection on the skin is used as a marker.

Results—The system is able to provide a full multifactorial description of a movement. This latter is thus objectively characterized. The flexibility of the front-end device allows the use of the system in very different fields of science. Body surfaces and volumes analysis seems to be a promising application of the system.

Recent Publications Resulting from This Research

- An Algorithm for 3-D Automatic Movement Detection by Means of Standard TV Cameras. Borghese NA, Ferrigno G, IEEE Trans Biomed Eng 37(12):1221-1225, 1990.
- A Hierarchical Approach to 3D Movement Analysis. Ferrigno G, SPIE Proceedings, 1356:2-7, 1990.
- Pattern Recognition in 3D Automatic Human Motion Analysis. Ferrigno G, Borghese NA, Pedotti A, ISPRS J Photogramm Remote Sens 45:227-246, 1990.
- A Technique for the Evaluation of Derivatives from Noisy Biomechanical Displacement Data Using Model-Based Bandwidth-Selection Procedure. D'Amico M, Ferrigno G, Med Biol Eng Comput 28:407-415, 1990.
- Elite: A Goal-Oriented Vision System for Moving Objects Detection. Borghese NA, Di Rienzo M, Ferrigno G, Pedotti A, Robotica 9:275-282, 1991.
- A Comparison Between the More Recent Techniques for Smoothing and Derivative Assessment in Biomechanics. D'Amico M, Ferrigno G, Med Biol Eng Comput (in press).

[86] Quantification of Tool Use by Amputees

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Sponsor: *National Institute on Disability and Rehabilitation Research; National Science Foundation; National Institutes of Health; Whitaker Foundation; Fairchild Foundation*

Purpose—Our goal is to quantify the motor performance of upper-extremity amputees and identify

those features of an amputation prosthesis which enable effective functional behavior.

Methodology—An externally-powered computer-controlled prosthesis emulator which can be worn by an above-elbow amputee and operated through any of the usual command channels (e.g., switch control, myoelectric activity, cable pull) has been developed. It can be programmed to mimic the behavior of any prosthesis—existing or proposed. The system is programmed to emulate an impedance-controlled prosthesis (which mimics the behavior of the natural arm); and the Boston Elbow and Hosmer/NY Elbow (both commercially available).

The upper extremity must frequently operate in the presence of a kinematic constraint (e.g., opening a drawer or sliding the hand along a tabletop). These tasks require coordinated action of both the natural and artificial segments. To assess this ability quantitatively, a simple test was devised: turning a crank in a vertical plane. We also measured amputee subjects' performance on tasks representing activities of daily living (ADL): 1) donning socks (a self-care activity); 2) simulated eating (cutting play-dough with ordinary eating utensils); and, 3) rolling play-dough with a rolling pin.

Progress—Experiments with four amputee subjects confirm the major results of earlier studies. The velocity-controlled prostheses require more abrupt and precisely timed changes of elbow torque than the impedance-controlled prosthesis. Yet observation of only motion and kinematic data shows little distinction between the control schemes. This indicates that the amputee adapts his motor strategies (e.g., by using "body English") to compensate for deficiencies of the machine. However, the need to compensate increases the difficulty of using the prosthesis.

Analysis of the mechanical power at the elbow showed that for significant portions of the crank-turning task, the velocity-controlled prostheses act to absorb power. The externally-powered prosthesis acts primarily as a complicated brake which opposes the action of other body segments in performing this task: this may explain slow acceptance by amputees.

In contrast, with the impedance controller performing the task, the prosthesis always acts to produce power and never absorb it: the prosthesis acts in synergy with other body segments. This confirms our hypothesis that the control system is a critical factor determining the usefulness of an

externally powered prosthesis.

Subjects performed two timed trials for the three ADL tasks. Completion time was used as a measure of performance of both ADL and crank-turning tasks. The rate of change of the elbow torque with respect to crank angle was computed as a quantitative measure of the performance of the crank-turning task. The time taken to complete the ADL tasks did not differ significantly for different prosthesis controllers. However, for the crank-turning task, performance with the impedance controller more closely resembled that of our able-bodied subjects than with the velocity-controlled prostheses: while moving along the crank path there was a smooth gradual change in elbow torque with the impedance controller versus the abrupt changes in elbow torque observed with the velocity controllers. The rate of change of the elbow torque with respect to crank angle was typically smaller for the impedance controller by a factor of four.

Results—Task completion times are commonly used in clinical practice for quantitative assessment because they are simple to measure. Results indicate that completion times alone do not provide sufficient information to distinguish between the functional benefits of different prostheses. With regard to ease of use, it is necessary to examine the more detailed information provided by other instrumentation such as biomechanical measures or myoelectric activity of selected relevant muscles.

Prior work on EMG processing led to a novel technique which improved the fidelity of myoelectric estimates of muscle action, though at the cost of increased complexity of the processing method. However, recent advances in personal computer technology no longer make this complexity a barrier to widespread use. Accurate calibration of the software is essential if a reliable estimate of muscle action is to be obtained. Prior methods of calibration have assumed that antagonist muscles are silent—an invalid assumption, especially in the clinical practice of rehabilitation, because abnormal patterns of antagonist co-contraction are common.

We have completed and tested new calibration methods which properly account for antagonist muscle activity. We found that simultaneous calibration of agonist and antagonist muscles provides superior results.

Recent Publications Resulting from This Research

EMG Amplitude Estimation From Temporally Whitened, Spatially Uncorrelated Multiple Channel EMG. Clancy EA, Hogan N, in Proceedings of the Annual International Conference of the IEEE Engineering in Medicine and Biology Society, 1990.

Functional Assessment of Control Systems for Cybernetic Elbow Prostheses. Part I: Description of the Technique. Abul-Haj CJ, Hogan N, IEEE Trans Biomed Eng 37(11):1025-1036, 1990.

Functional Assessment of Control Systems for Cybernetic Elbow Prostheses. Part II: Application of the Technique. Abul-Haj CJ, Hogan N, IEEE Trans Biomed Eng 37(11):1037-1047, 1990.

Mechanical Impedance of Single- and Multi-Articular Systems. Hogan N, in Multiple Muscle Systems: Biomechanics and Movement Organization, 149-164, J. Winters, S. Woo (Eds.). New York: Springer-Verlag, 1990.

Principles Underlying Movement Organization: Upper Limb. Hogan N, Winters JM, in Multiple Muscle Systems: Biomechanics and Movement Organization, 182-194, J. Winters, S. Woo (Eds.). New York: Springer-Verlag, 1990.

A Simple Competent Model of the Maintenance of Elbow Posture in the Presence of Disturbances. Murray WR, Hogan N, in Issues in Modeling and Control of Biomechanical Systems, 25:7-21, J.A. Ashton-Miller, M.G. Pandy (Eds.). New York: ASME, 1990.

Assessment of Multiple-Joint and ADL Tasks Performed by Above-Elbow Amputees. Kishinchandani RS et al., in Proceedings of the American Physical Therapy Association Annual Conference, 1991.

Estimation of Joint Torque from the Surface EMG. Clancy EA, Hogan N, in Proceedings of the Annual International Conference of the IEEE Engineering in Medicine and Biology Society (in press).

[87] Head Movements in Severely Disabled People

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Sponsor: North Lincolnshire Health Authority

Purpose—Clinical experience suggests that a significant proportion of people with severe disabilities need to use head movements to control assistive equipment. The literature is largely device-led, with few papers dealing with head movement interfaces and their users in a systematic or quantitative way.

This project is investigating how severely handicapped people move their heads and what models are appropriate to describe their head movement control.

Progress/Methodology—A video-based remote viewing system was developed and is now being used to collect data in two dimensions from subjects seated below the camera, wearing a helmet on which two light sources are mounted. Subjects perform fast movements between two points which are analyzed at 25 fields/sec. Light source coordinate values from the video image are plotted against time.

Preliminary Results—Results from nondisabled subjects show a typical second-order response to a step input. Values for delay, rise time, and damping ratio are being obtained.

Future Plans/Implications—Parameter value ranges will be explored for subjects with cerebral palsy and multiple sclerosis and compared with data from nondisabled subjects. These results will be used in conjunction with a simple head movement control model to explore which parameters are of most importance for quantitative assessment. This information can also be used by assistive equipment designers.

Recent Publications Resulting from This Research

A Video Signal Analyser with Applications for Head Movement Monitoring of Severely Handicapped People. Dymond EA et al. Med Biol Eng Comput (in press).

[88] Reliability of the ASHA Functional Communication Measure for Cognitive-Communication

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Sponsor: Rehabilitation Institute of Michigan

Purpose—Speech-language pathologists are increasingly responsible for documenting progress in order to gain and continue service eligibility for head trauma patients. One method of obtaining this documentation is through the use of outcome measurement instruments. While the American Speech-Language Hearing Association (ASHA) Functional Communication Measure for Cognitive-Communication (FCM:CC) appears to have potential in allowing clinicians to effectively track the progress that head trauma patients make as a result of cognitive-communication treatment, there have been no reliability/validity investigations conducted to substantiate its use. Two investigations were conducted to establish several of the needed validity/reliability measures for the FCM:CC.

Methodology—In the first investigation, five certified speech-language pathologists rated patients with diagnoses of closed-head injury on a weekly basis during their inpatient rehabilitation programs using the FCM:CC and the Disabilities Ratings Scale (DRS); 132 pairs of data points were collected. Spearman rho correlation coefficients were calculated to determine the pattern of agreement for raters on the two measures.

In the second investigation, nine certified staff speech-language pathologists who specialize in the treatment of head trauma collected videotaped 20-minute segments of 24 traumatically brain-injured clients whose cognitive-communication behaviors were representative of the range of the FCM:CC. Each of the staff followed a standard format for eliciting the behaviors.

Thirty certified speech-language pathologists, with no less than 2 years' experience in the treatment of clients with cognitive-communication disorders resulting from head injury, participated as raters in this study. Raters represented a variety of work settings across several of the United States and provinces of Canada.

By random assignment, 15 of the raters were trained (TR) and 15 were untrained (UTR). The TR were exposed to a 20-minute videotape and training manual which defined the scale points of the FCM:CC. TR and UTR were matched and randomly assigned to one of three subgroups of 10 raters. A total of 24 clients whose behaviors were representative of the range of the FCM:CC were included in the sample.

All TR and UTR provided independent FCM:CC ratings for one of three subgroups of eight head-injured clients based on information they obtained from videotaped sessions and excerpts from their medical charts. Prior to making ratings, TR completed a decision-making checklist for each client being rated.

Kappa coefficients of agreement will be calculated (κ) to determine the exact proportion of agreement among pairs of raters for each group of clients being rated. κ is equal to the proportion of agreement between pairs of raters after chance agreement is removed from consideration. Using a mixed analysis of variance design, F ratios will be calculated to determine the significance of the main effect training has on the interrater reliability of the FCM:CC.

Preliminary Results—Results of the first investigation yielded rho correlation coefficients for pairs of judges (>0.800) that were substantial and a highly significant correlation coefficient between the FCM:CC and the DRS (0.93), evidence of concurrent validity of the FCM:CC. However, further analysis suggested that the scale items of FCM:CC lacked the definitional clarity necessary to achieve exact agreement among judges. Improving exact judge agreement was of clinical importance since treatment decisions are based upon classification levels. The data regarding the effect of training on interrater reliability of the ASHA FCM:CC are currently undergoing analysis.

[89] Development of a Movement Training and Assessment System for the Upper Limb

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Sponsor: *Scottish Home and Health Department*

Purpose—The purpose of this development was to produce a piece of apparatus to facilitate upper limb rehabilitation in the form of an exercise device linked to a microcomputer. The microcomputer software was designed to provide motivating activities associated with the various movements of the device and also to enable measurement of maximum torque and work rate to be made, thereby enabling therapeutic progress to be evaluated.

Methodology—The resistive element of the device takes the form of a rotary dashpot in which a viscous fluid is sandwiched between rotating plates. The resistance of the device can be altered by adjusting the separation of the plates. An important feature of the dashpot is that resistance is proportional to angular velocity. It is low for slow rotation and becomes much more difficult as the speed of

rotation increases. Because of this feature, it is unlikely that a patient will be overstressed.

Results—The clinical role of this device has been evaluated in a number of centers throughout the United Kingdom with encouraging results. The interest shown by rehabilitation departments stimulated efforts to make the device available commercially and this has now been achieved through a retail company (Nottingham Rehab Ltd., West Bridgford, Nottingham, UK).

The device at present is based on a British Broadcasting Company (BBC) microcomputer. This choice was influenced by the ready availability of the BBC micros in rehabilitation units throughout the UK following a previous DTI initiative. A modification to enable the system to be used on a conventional PC was released in late 1991.

[90] Clinical Measurement System for the Movements of Rising to Stand and Sitting Down

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Sponsor: *Scottish Home and Health Department*

Purpose—The objective of this proposal has been to establish a clinical measurement system, for use in a rehabilitation setting, that is capable of measuring aspects related to rising to stand and sitting down.

Progress/Preliminary Results—A clinical measurement system has been established comprising a modified chair with strain-gauged arm sections and a four-cell force sensitive steel platform on which the patients stand. The measuring devices are connected to a BBC Archimedes 440 Microcomputer via strain-gauge amplifiers and a 12-bit analog digital converter. Purpose-written software has been developed to control the patient test, data storage, and

data presentation. Hard copy of the results can be produced for immediate entry into patient records. Thirty-six subjects, all adult hemiplegics undergoing a program of rehabilitation, have been tested using this system. The data are currently being analyzed.

Recent Publications Resulting from This Research

A Clinical Measurement for the Movements of Rising to Stand and Sitting Down. Durward BR, et al., in Proceedings of the 6th International Conference on Biomedical Engineering, Singapore, 138-140, 1990.

A Clinical Measurement System for the Movements of Rising to Stand and Sitting Down. Durward BR, Rowe PJ, in Proceedings of the World Confederation for Physical Therapy 11th International Congress, London, UK, 1292-1294, 1991.

IV. Functional Electrical Stimulation

A. General

[91] Comparison of Percutaneous Pudendal Nerve and Surface Electrical Stimulation for Bladder Inhibition: A Pilot Study

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Sponsor: VA Rehabilitation Research and Development Service (Project #B996-PA)

Purpose—Bladder hyperreflexia in spinal cord injured (SCI) patients can cause upper urinary tract pathology and urinary incontinence. There have been many techniques developed to inhibit the bladder in these patients with limited success, including pharmacological and surgical techniques. Electrical stimulation has been introduced as an alternative technique. Bladder inhibition with pudendal and sacral nerve stimulation was observed in the SCI cat model. Inhibition with electrical stimulation was observed in the SCI patients while using various methods of stimulation including: sacral surface, surface tibial nerve, rectal, percutaneous pudendal nerve, and surface dorsal penile stimulation. However, dorsal penile stimulation seems to be the most effective stimulation technique for inhibiting the bladder.

Progress—Dorsal penile nerve electrical stimulation was demonstrated to be an effective method of inhibiting bladder hyperreflexia, acutely, in SCI males. A clinical trial to test this technique on SCI patients for chronic use at home is planned.

Methodology—Six chronic suprasacral SCI males with bladder hyperreflexia, but otherwise healthy, underwent baseline water cystometry (CMG), at a 60 cc/min fill rate using a two-channel catheter. Repeat CMG was done at 15-minute intervals to assure reproducible baseline results. For stimulation, two disposable carbon rubber butterfly electrodes were placed in sequence along the dorsum of the penis.

Stimulation was conducted with a neuromuscular stimulator producing capacity coupled pulses with the voltage monitored via an isolated oscilloscope. Stimulation parameters were 5 pulses per second (pps) at 0.35 m/sec pulse duration and a current that caused minimal visible pelvic twitching activity (20-40 ma), the threshold. Progressively higher or lower currents were attempted during CMG, to assess the efficacy of the stimulation on bladder filling volume. A control CMG was done after each stimulation trial. Cardiovascular monitoring was done during stimulation.

Results—The six patients averaged 36 years of age, and 5.3 years from date of SCI. All six patients had bladder sphincter dyssynergia. There was a significant increase in CMG filling volume from an average of 187 ml at baseline to 328 ml during penile stimulation, an average of 76% increase. The average poststimulation filling CMG volume was 248 ml, which was also higher than baseline. In two patients, the penile stimulation suppressed bladder function totally. After stimulation was turned off, the two patients had spontaneous bladder contractions. The average current required to suppress bladder activity was 42.5 ma, with most patients requiring current at or above the threshold. There were no side effects from the stimulation.

Future Plans—The goal is to decrease the bladder hyperreflexia of SCI patients and the resultant incontinence and morbidity associated with it. Dor-

sal penile surface electric stimulation is an effective, easily applied stimulation technique for inhibiting the bladder. Chronic testing using specific dorsal surface penile electrodes and a portable stimulator is planned.

Recent Publications Resulting from This Research

Treatment of Incontinence in the Spinal Animal Model: Comparison of Pudendal and Sacral Nerve Electrodes. Walter

JS, et al., in Proceedings of the American Paraplegic Society, Las Vegas, 26, 1990.

Bladder Inhibition by Penile Nerve Stimulation in Spinal Cord Injured Patients. Wheeler JS, et al., in Proceedings of the American Paraplegia Society, Las Vegas, 1991.

Bladder Inhibition by Penile Nerve Stimulation in Spinal Cord Injured Patients. Wheeler JS, et al., J Urol (in press).

[92] Sputtered Iridium Oxide Films (SIROF) as High, Bipolar Charge Injection Coatings for Implanted Stainless Steel Electrodes

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Sponsor: VA Rehabilitation Research and Development Service (Project #B658-RA)

Purpose—The application of implantable neuroprosthetics for functional neuromuscular stimulation (FNS) has gained wide acceptance. Applications have included control of upper and lower limbs, respiration, and bladder function. Various brain stimulation methods have been used for chronic pain problems and movement disorders most often involving spasms. Despite the widespread use of FNS, there are several problems and shortcomings associated with stimulation electrodes that limit the versatility and longevity of FNS systems in clinical applications. Dysfunction of electrodes due to lead breakage, corrosion, or electrode migration has continued to limit *in vivo* electrode life. The objective of this program is the identification of electrode coatings and stimulation protocols that allow significant bipolar charge injection from high strength stainless steel (316LVM) and the more recently developed Co-based alloy MP35N wire, typically used in FNS electrode leads.

With the exception of a small capacitive contribution from the double-layer, faradaic oxidation-reduction reactions mediate charge transfer across the electrode-electrolyte interface during stimulation. The principal objective in choosing an electrode coating is to identify one in which these faradaic processes are reversible, minimize electrode corrosion, and produce no adverse physiological effects. Sputtered iridium oxide films (SIROF), which undergo reversible, faradaic, valence-change reactions at a substantially higher charge injection

capacity than the uncoated 316LVM and MP35N alloys, are being investigated as electrode coatings. The use of SIROF as a charge injection coating is intended to serve a dual purpose. The SIROF will increase the charge injection capacity of the electrode and allow the use of 316LVM and MP35N leads in a bipolar configuration. The higher bipolar charge capacity should provide latitude in the choice of electrode area and stimulation protocol. Second, the SIROF should minimize corrosion-related failures of 316LVM and MP35N leads, particularly those associated with anodic potential excursions (breakdown of passivity) or nonuniform current distributions.

Progress/Methodology—In preliminary studies, we compared potential excursions of multistranded stainless steel (316LVM) and SIROF-coated 316LVM electrodes (Cooner) during charge injection in a phosphate-buffered saline solution. The SIROF was deposited on the electrode by reactive RF sputtering in an O₂/Ar/H₂O gas mixture. The stimulation parameters were 30 mA, 350 μ s, monophasic, cathodic-first pulses capacitively coupled at a repetition rate of 20 pps. This stimulation protocol results in a charge injection density of 105 μ C/cm² based on the calculated geometric area of the electrode. The current and potential transients, measured with a saturated calomel reference electrode and corrected for the initial iR drop, were recorded with an oscilloscope. The access resistance

of the SIROF-coated electrodes was reduced by approximately 40%. The lower access resistance was particularly evident from the potential transient in the discharge phase which more rapidly approached the initial interpulse potential (electrode depolarization), due to the shorter overall RC time constant of the discharge circuit. The potential transients during the cathodic pulse were also greatly reduced by the SIROF coating.

Future Plans—We plan to evaluate the electrochemical stability and adhesion of SIROF-coated 316LVM, MP35N, and tantalum electrodes with monophasic and biphasic stimulation protocols to provide a preliminary *in vitro* assessment of their suitability as implantable stimulating electrodes.

Recent Publications Resulting from This Research

Evaluation of a 316LVM "Woven Eye" Electrode for Direct Bladder Stimulation. Walter JS, et al., IEEE Trans Biomed Eng (in press).

[93] Electrical Activation of the Diaphragm for Ventilatory Assist

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Sponsor: VA Rehabilitation Research and Development Service (Project #B634-RA)

Purpose—The purpose of this study is to complete the preclinical studies of chronic electrical stimulation for ventilatory assist through activation of the phrenic nerve with an electrode at the diaphragm muscle. In the past, ventilatory pacemakers have primarily used cuff electrodes placed on the phrenic nerve in the neck or thorax. Our animal research has demonstrated that activation of the phrenic nerve, through electrodes placed directly into the diaphragm muscle, can eliminate many of the risks of traditional phrenic nerve pacers and provide more extensive clinical use for electrically induced ventilation. Additional work in the clinic has indicated a new type of electrode for the pacing of the diaphragm. The electrode will be an epimysial electrode sewn onto the abdominal surface of the diaphragm. Additionally, a new laparoscopic implant procedure will need to be developed. The electrode design and development of the implant procedure has pre-empted clinical application of the device.

Progress/Methodology—Progress includes work on the design of an epimysial electrode, initiation of work on implant of the electrode and meeting the regulatory requirements.

Epimysial Electrode Design. Design has been nearly completed of an epimysial electrode for diaphragm pacing. The design incorporates the latest technology in electrode electrochemistry and

mechanical design. The electrode uses a titanium electrode with an iridium oxide coating placed within a well. This design is based on computer simulations of the current at the electrode surface and promises to be electrochemically safe.

The mechanical design of the electrode has become a critical issue in the design of the electrode. An interface of titanium and stainless steel is necessary for connecting the lead wire to the electrode. The weld of these two metals has been studied using a set of three tests: a tensile test, a scanning electron microscope (SEM) study of the weld break, and an energy dispersive X-ray (EDAX) analysis of the weld break. The weld has been optimized for maximum strength and finishes the work on the mechanical design of the electrode.

Electrode Implant. The epimysial electrode will be implanted using a laparoscopic procedure. Preliminary work has been done on a device to deliver the electrode to the implant site and temporarily fix it to the muscle for suturing. A modification of the electrode delivery device will be useful for laparoscopic mapping of the diaphragm. This device needs to be further developed during animal surgery.

Meeting Regulatory Requirements. We are in the process of preparing an investigational device exemption (IDE) for the FDA. The IDE entitled "Electrical Activation of the Diaphragm Muscle for

Respiration Assist Using Percutaneous Intramuscular Electrodes," is complete.

Future Plans—In the next year, testing of the epimysial electrode will be completed. This testing

includes an *in vitro* test of the electrode as well as a complete long-term animal test. The implant procedure will be developed in a short-term set of experiments. The diaphragm stimulation system will then be implemented in a clinical setting.

[94] Improving Exercise Performance of Quadriplegics

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Sponsor: VA Rehabilitation Research and Development Service (Project #B587-RA)

Purpose—The purpose of this 3-year project is to develop and evaluate an arm + leg exercise system for spinal cord injured (SCI) quadriplegics that maximizes active muscle mass and aerobic metabolism and allows adequate central and peripheral circulation. Arm-cranking is used to drive the leg cycling motion, while a computer controls the functional neuromuscular stimulation (FNS) of appropriate leg muscle groups during the crank cycle to assist leg cycling. Phase I consists of development and construction of a voluntary-arm + FNS-leg ergometer to permit operation in either the upright sitting or supine posture. Phases II and III consist of evaluation of acute and chronic physiologic responses of quadriplegics during exercise testing and training with this device.

Progress—Construction is nearing completion on the new ergometry system. The base structure has been redesigned to allow upright and (up to 30 degree) reclined arm and leg cycling. Hip angle will be maintained at a constant 60 degrees of flexion.

This will control for biomechanical differences between cycling in the two positions (i.e., gravitational orientations). Four pedal force transducers with a split-ring arrangement and four amplifiers have been built to allow measurement of the independent contributions of each arm and leg to the total power output. A 16-channel electrical stimulator has been built (35 Hz frequency, 0.300 msec pulse width, 0-150 mA current output). All software has been completed for data acquisition and control of electrical stimulation. The cycling cadence (rpm) will be used to control the timing of electrical stimulation in the various leg muscles. Voluntary arm-cranking will control the cycling cadence. The electrical stimulation intensity will be controlled by the operator via the computer software. The operator's computer display will contain the heart rate of the user, cycling cadence, power output for each arm and leg, stimulus intensity for each muscle group, and relative proportion of arm and leg power output.

[95] Evaluation of FES Techniques for Exercise

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Purpose—The purpose of this project was to evaluate the effectiveness of functional electrical stimulation (FES) exercise techniques for improving health,

physical fitness, and rehabilitation potential of patients with spinal cord injury (SCI). Specific objectives included: 1) assessment of acute physio-

logic responses and maximal performance during FES leg cycling (FES-LCE) exercise, FES knee extension (FES-KE) exercise, voluntary arm-crank exercise (ACE), and combined FES-LCE + ACE (HYBRID) exercise; and, 2) determination of physiologic and psychologic adaptations resulting from training with the various FES/voluntary exercise modes.

Progress—About 100 SCI individuals have participated in some aspect of this study. Of these, 30 subjects have completed at least one of the four 12-week training programs involving FES-induced exercise: 12/FES knee extension training; 20/ERGYS training; 14/serial FES-LCE and ACE training; 15/hybrid training; and, 10/an additional phase of interval training using FES-LCE. In addition, several substudies have been conducted including: kinematic biomechanical analysis of FES exercise; spasticity of paralyzed muscles; fatigue/performance characteristics of paralyzed muscles (i.e., FES current versus force development); bone density assessments; incorporating a motorized device on the FES-LCE to assist weak subjects; and, bioengineering analysis of the FES-LCE to analyze how operation may be optimized. Questionnaires designed to assess the health status of participants are being analyzed.

Preliminary Results—FES-KE training significantly increased the strength and endurance of the paralyzed quadriceps muscles and knee range of motion. FES-LCE training significantly increased maximal power output, peak oxygen uptake, cardiac output, and pulmonary ventilation. HYBRID exercise elicited additive metabolic and cardiopulmonary responses, and may provide for greater aerobic training capability than ACE or FES-LCE individually, especially in quadriplegics. Databases for these studies are being expanded as additional subjects complete the exercise training programs.

Changes in paralyzed muscle strength and endurance with FES exercise training have been documented using a computerized force-current measurement system. The 108 tests utilizing repetitive isometric contractions of the quadriceps muscles

demonstrated increased force development per unit of FES current, maximal force capability, and resistance to fatigue while performing the given task.

Tibial bone density measurements (using quantitative computed tomography) on 15 subjects before and after FES-LCE and/or FES-KE resistance exercise training revealed less loss in trabecular bone at the distal and proximal ends than expected in comparison with the predicted loss curves from the cross-sectional data. Average reduction in loss was between 1.67 and 3.31% per year depending on site and compartment evaluated.

Future Plans/Implications—From our experience with existing FES exercise techniques, we plan to refine the FES instrumentation and training protocols in order to optimize physiologic adaptations. It appears that SCI patients can derive clinical benefits from FES exercise therapy which can contribute to their health, fitness, and rehabilitation potential.

Recent Publications Resulting from This Research

- Cardiorespiratory Fitness Following Spinal Cord Injury. Davis GM, Glaser RM, in *Key Issues in Neurological Physiotherapy*, 155-196, L. Ada, C. Canning (Eds.). London: Heinemann Medical Books, 1990.
- Functional Neuromuscular Stimulation for Physical Fitness Training of the Disabled. Glaser RM, in *Fitness for Aged, Disabled and Industrial Workers*, 127-134, M. Kaneko (Ed.). Champaign, IL: Human Kinetics Publishers, 1990.
- Perspectives on Cardiovascular Fitness and SCI. Figoni SF, *J Amer Paraplegic Soc* 13:63-71, 1990.
- Acute Hemodynamic Responses of SCI Individuals to Functional Neuromuscular Stimulation-Induced Knee Extension Exercise. Figoni SF, et al., *J Rehabil Res Dev* 28(4):9-18, 1991.
- Adaptive Control of Functional Neuromuscular Stimulation-Induced Knee Extension Exercise. Ezenwa BN, et al., *J Rehabil Res Dev* 28(4):1-8, 1991.
- Exercise Conditioning of the Spinal Cord Injured Via Functional Electrical Stimulation. Glaser RM, in *Athletic Injuries to the Head, Neck and Face* (2nd ed.), 553-565, J.S. Torg (Ed.). Chicago: Yearbook Medical Publishers, 1991.
- Musculoskeletal Responses of Spinal Cord Injured Individuals to Functional Neuromuscular Stimulation-Induced Knee Extension Exercise Training. Rodgers MM, et al., *J Rehabil Res Dev* 28(4):19-26, 1991.
- Use of Threshold Current Changes as an Index of Responsiveness and Fatigability in Paralyzed Muscle During FNS. Kuntzman AJ, et al., in *Proceedings of the 14th Annual RESNA Conference*, 292-293, 1991.

[96] FNS Effects Upon Venous Pooling in Geriatric and Mobility-Impaired Patients

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Sponsor: VA Rehabilitation Research and Development Service (Project #B242-3RA)

Purpose—The overall purpose of this research program is to evaluate the acute effects of pulsatile functional neuromuscular stimulation (FNS)-induced contractions of leg muscles upon central and peripheral hemodynamic responses to determine if venous pooling/stasis and edema can be prevented and/or alleviated in mobility-impaired and geriatric patients. Specific objectives are to evaluate the effectiveness of this FNS application for facilitating circulation during head-up tilt, upright sitting, standing, arm-crank exercise, and wheelchair propulsion.

Progress—Instrumentation designed and constructed for implementing this research program includes: 1) 8-channel neuromuscular stimulators to alternately contract thigh and calf musculature with adjustable on-off patterns; 2) a motorized tilt table with adjustable arm-crank ergometer to allow arm-crank exercise during tilting; 3) a lower-body negative/positive pressure chamber to simulate various gravitational loads on venous blood columns; 4) an eight-segment impedance cardiographic/arteriographic data collection and computer analysis system (hardware and software) to monitor central and peripheral circulation; and, 5) a system that measures bioelectrical resistance, reactance, and impedance in eight segments of the body simultaneously for assessment of segmental fluid shifts and volumes. Both impedance systems are being used to assess physiologic responses during postural change and arm exercise, and to evaluate the effectiveness of FNS-activation of the skeletal muscle pump for minimizing venous pooling and enhancing venous return. Over 60 geriatric hemiplegics and other disabled subjects were initially screened for participation, and given an orthostatic tolerance test. About 30 subjects have undergone head-up tilt tests, and prolonged upright sitting tests incorporating pulsatile FNS-induced contractions of the calf and thigh muscles. They are presently participating in

arm exercise tests and tests to compare clinically used mechanical pressure devices to the FNS technique.

Preliminary Results—Data from these studies indicate that this FNS technique can significantly enhance venous return of blood to the heart. This was demonstrated by reduced blood volume (pooling) in the legs and increased ventricular stroke volume and cardiac output. This effect occurred in the supine and sitting positions, as well as during head-up tilt to +70 degrees. These effects were also observed during lower-body negative pressure from -15 to -45 Torr. During arm exercise by SCI subjects, FNS was found to significantly enhance venous return of blood to the heart as indicated by increased ventricular stroke volume and cardiac output. These effects were observed in the supine and sitting positions, as well as head-up tilt to +30 degrees.

Future Plans/Implications—If this FNS application can reduce venous pooling in the legs and improve circulation to exercising arm muscles, it may be able to enhance arm exercise capacity, decrease the stressfulness of manual wheelchair locomotion, and improve the tolerance for upright postures for prolonged durations. Future medical and rehabilitative applications may also include prevention of deep venous thrombosis in immobilized or postsurgical patients and treatment of orthostatic hypotension, excessive pedal edema, and decubitus ulcers in susceptible individuals.

Recent Publications Resulting from This Research

Cardiovascular Responses to Arm Cranking and FNS-Induced Leg Exercise in Paraplegics. Davis GM, et al., *J Appl Physiol* 69:671-677, 1990.

Cardiovascular Problems of the Wheelchair Disabled. Glaser RM, in *Exercise and the Heart in Health and Cardiac Disease*, R. Shephard, H. Miller (Eds.). Toronto: B.C. Decker, Inc. (in press).

[97] Bases of Magnetic Brain Stimulation

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Sponsor: Emory University-Georgia Tech Biomedical Research Foundation; VA Medical Center (Core Funds)

Purpose—Magnetic brain stimulation (MBS) is used increasingly to study the physiology of human motor systems in health and disease. Cognitive applications are developing gradually as well. Improved usage of MBS and verification of its long-term safety require a better understanding of its effects within the nervous system. The Atlanta VAMC Rehab R&D Center has been developing physical and theoretical models of electromagnetic fields in tissue, and improving the localization of their effects.

Progress/Methodology—The Rehab R&D Center has contributed to the design and construction of two specialized magnetic stimulators, and to improved stimulus coils for a third, commercial device. With support from the Emory-Georgia Tech Biomedical Research Foundation, Dr. Davey supervised construction of the first practical high-speed iron-core stimulator. In cooperation with Drs. Robert Green and Steven Hersh at Emory, this device has been applied to safety studies of magnetic stimulation in mice. Construction of the second specialized stimulator and modeling of magnetic effects in tissue allowed the first practical localization of the stimulus site within the human motor cortex.

Theoretical analysis has produced simplified techniques for calculating the effects of circular magnetic stimulus coils in tissues of arbitrary shape and composition. The combination of mathematical and physical modeling has elucidated the critical relationship between the efficiency of magnetic

brain stimulation and brain size, which will be vital to all future studies in small animals. Physical modeling and coil design have utilized test and measurement equipment provided by core funding at the Rehab R&D Center. Human and animal studies have been carried out using subjects and facilities at Emory University School of Medicine.

Future Plans/Implications—Having demonstrated that magnetic stimulators designed for human brains are generally unsuitable for small animals, the investigators plan to build an iron-core stimulus coil dedicated to animal research. Long-term safety studies of MBS using more effective stimuli for laboratory animals can be completed with the new coils. Such studies remain essential for widespread use of MBS. Combining localization of MBS stimulation with theoretical analysis will allow the analysis of the effects of brain inhomogeneities on neuronal depolarization. The original rapid iron-core stimulator is suitable for cognitive studies in humans, but its use is uncomfortable; studies of other materials are being conducted to overcome this limitation.

Recent Publications Resulting from This Research

Cervical Magnetic Stimulation: The Role of the Neural Foramen. Epstein CM, et al., *Neurology* 41:677-680, 1991.

Prediction of Magnetically Induced Electric Fields in Biological Tissue. Davey KR, Cheng CH, Epstein CM, *IEEE Trans Biomed Eng* 38:418-422, 1991.

Magnetic Brain Stimulation and Brain Size: Relevance to Animal Studies. Weissman JR, Epstein CM, Davey KR (Abstract). *J Clin Neurophysiol* (in press).

[98] Therapeutic Effects of Functional Electrical Stimulation on Paralyzed Persons

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Purpose—The purpose of this project is to demonstrate the effectiveness of electrical stimulation (ES) on muscle performance, muscle blood flow, and bone density in spinal cord injured (SCI) subjects, and on muscle performance, walking ability, and daily function in hemiplegic patients.

Methodology—SCI subjects participate in a 3-month standing protocol followed by a 3-month standing and ES protocol (Rancho REP portable stimulator, cutaneous electrodes, Axelgard Mfg). Dual photon absorptimetry is used to assess bone mineral density, xenon washout determines quadriceps blood flow, and muscle performance is assessed by an integrated ES and exercise dynamometry system (Rancho REP/LidoActive System). Open circuit spirometry documents efficiency of ES exercise. Hemiplegic patients who lack hip stability for stance and/or limb advancement for swing receive implanted (epimysial) electrodes to augment hip and thigh muscle function. Kinesiological electromyography is employed to aid in the selection of key muscles for implantation. Exercise dynamometry and instrumented gait analysis document change in performance.

Progress/Preliminary Results—The findings to date indicate that peak knee extension moment, the amount of knee extension work performed and quadriceps fatigue resistance are improved significantly by a 3-month ES protocol in SCI. Improvements in peak moment were associated with a reduction in quadriceps and hamstring spasticity and reduced knee crepitus. The improvements were not

only statistically significant, but indicate that ES muscle performance can meet the demands of both double and single limb support for walking. Improvement in efficiency of ES knee extension exercise indicates that SCI patients may expect to perform knee motion at an energetic expenditure similar to that of normal subjects working at a similar exercise intensity. As expected, ES does increase muscle blood flow during stimulation, but changes in resting blood flow and bone density await further analysis.

Percutaneous epimysial electrodes permit the ES activation of deep hip muscles that are not accessible with cutaneous electrodes. The gluteus medius and maximus, as well as the adductor magnus, have proved effective in augmenting stance stability. The biceps femoris, long head, is effective when there is no tendency for knee flexion during stance. The biceps femoris, short head, sartorius and iliacus augmented limb flexion. The 8-channel programmable stimulator has adequately supported the stimulation requirements for the hemiplegic patients for cyclical and footswitch-controlled stimulation. Correction of gait deviations at the hip and knee has resulted in improved stride characteristics and safety in ambulation.

Recent Publications Resulting from This Research

Efficiency of Electrically Stimulated Exercise: Normal vs. SCI. Campbell J et al., Proceedings of the 14th Annual RESNA Conference, Kansas City, MO, 286-288, 1991.

Multichannel Electrical Stimulation System for Gait Assist and Cyclical Stimulation. Meadows P et al. Proceedings of the 14th Annual RESNA Conference, Kansas City, MO, 391-393, 1991.

[99] Prevention of Secondary Complications in Spinal Cord Injury by Electrical Stimulation: Wheelchair-Attached Balance Frame

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Sponsor: *National Institute on Disability Rehabilitation Research*

Purpose—Our objective is to establish a protocol for selecting and training appropriate patients to use a wheelchair-attached balance frame in conjunction with a 2-channel stimulator to achieve transient periods of standing on a repeatable basis. We hypothesize that the wheelchair-attached balance frame will be accepted by patients as a device that does in fact enhance their activities of daily living and mobility.

Progress/Methodology—A total of five individuals have now had field experience with the wheelchair-attached balance aid. Twelve individuals have had experience with the device in a controlled clinical setting. Standing time data indicates a frequency of use of greater than 10 times per week; however, patient comments have not been as positive as we

had hoped. Patients often feel that the wheelchair aid is clumsy for frequent use. A total of four standing frames are now in the field evaluation, but only one is in use in the home.

Preliminary Results—The major problem that appears to be preventing wider patient acceptance of the wheelchair-attached balance aid is postural stability when attempting to release one hand to perform functional tasks. We have tried adding ankle-foot orthoses to enhance stability in two subjects, but trunk balance is a more difficult problem to solve. The transition from quiet standing in a controlled laboratory or clinical situation to field use will depend on correctly identifying the improvements that need to be made.

[100] Computer-Controlled Orderly Stimulation of Motor Units in Various Strategies

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Sponsor: *National Science Foundation*

Purpose—The objective of this project was to develop and refine an electrical stimulation system that would allow orderly recruitment of motor units simultaneously with firing rate changes in various control strategies similar to physiological modes known to occur under voluntary contraction. Such an approach will allow smooth force generation, drastic reduction in fatigue, and possible damage to muscles.

A computer-controlled stimulation system was designed, developed, and validated in a series of experiments which explored muscle dynamic properties which were not available to date. Further development reduced the number of nerve electrodes from two bipolar cuffs into a single tripolar cuff. It was found that similar results could be obtained with intramuscular wire electrodes inserted in the

motor point as well. Recent work focused on application of the technique in identifying the muscles dynamic response model and in studying the EMG-force relationship for purposes of applications in a closed-loop functional electrical stimulation.

Recent Publications Resulting from This Research

EMG Power Spectra Frequencies Associated with Motor Unit Recruitment Strategies. Solomonow M, et al., *J Appl Physiol* 68:1177-1185, 1990.

The Effect of Tendons Viscoelastic Stiffness on the Dynamic Response of Isometric Muscle. Baratta R, Solomonow M, *J Biomech* 24:109-116, 1991.

The EMG-Force Relations of a Single Muscle Acting Across the Joint. Solomonow M, et al., *J Electromyog Kinesiol* 1:58-67, 1991.

The Dynamic Response of a Load Moving Muscles. Baratta R, Solomonow M, *J Appl Physiol* (in press).

[101] Development of Muscle Models for FES Applications

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Sponsor: National Science Foundation

Purpose—The purpose of this project was to identify and develop a comprehensive model describing the dynamic performance of a skeletal muscle for purposes of developing the optimal functional electrical stimulation (FES) controller for applications in case of paralysis due to spinal cord injury and stroke.

Results—We found that the dynamic response model of a skeletal muscle is nonlinear when using firing rate changes in the FES input. A reasonably linear model results, however, if the stimulation applied follows orderly recruitment. Various recruitment control strategies do not affect the model.

It was also found that different skeletal muscles have a similar general model, yet large variations exist in the coefficients employed in their mathemat-

ical description. These variations are due to variability in muscle architecture. Similarly, the model associated with isotonic contraction is based on that developed for isometric conditions, yet accounts for additional physical factors. The tendon was not found to make significant contributions in isometric conditions.

Recent Publications Resulting from This Research

The Dynamic Response Model of Nine Different Skeletal Muscles. Baratta R, Solomonow M, *IEEE-Trans BME* 37:243-251, 1990.

The Effect of Tendon Viscoelastic Stiffness on the Dynamic Performance of Muscle. Baratta R, Solomonow M, *J Biomech* 24:109-116, 1991.

Dynamic Performance of A Load Moving Muscle. Baratta R, Solomonow M, *J Appl Physiol* (in press).

[102] EMG as a Force Feedback in Electrically Stimulated Muscle

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Sponsor: National Science Foundation

Purpose—Force feedback is necessary if regulation of stimulated muscle force output is anticipated. Since implantation of force sensors requires traumatization of the tendon, the electromyogram (EMG) is considered as a parameter representing force in a closed-loop paradigm.

Progress—To date, we determined the relations between EMG and stimulated muscle force after developing a sophisticated artifact suppression system. The relations were evaluated as a function of stimulation strategies (recruitment and firing rate), contraction rate, muscle length, joint angle, and muscle moment arm. Additional work determined

that the mean absolute value of the EMG is the most representative signal-processing mode for prediction of force.

Recent Publications Resulting from This Research

The EMG-Force Relations of Skeletal Muscle: Dependence on Contraction Rate and Motor Units Control Strategy. Solomonow M, et al., *EMG Clin Neurophysiol* 30:141-152, 1990.

EMG Power Spectra Frequencies Associated with Motor Unit Recruitment Strategies. Solomonow M et al., *J Appl Physiol* 68:1177-1185, 1990.

EMG-Force Relations of a Single Skeletal Muscle Acting Across a Joint: Dependence on Joint Angle. Solomonow M, Baratta R, D'Ambrosia R, *J Electromyog Kinesiol* 1:58-67, 1991.

[103] A Silicone-Based Multichannel Interface to the Central Nervous System

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Sponsor: National Science Foundation; W.M. Keck Foundation; The William H. and Mattie Wattis Harris Foundation

Purpose—To create general-purpose, silicon-based multichannel interfaces to the central nervous system. These can be used to provide limited sensory restoration (artificial vision and hearing) and/or volitional control signals which can be used to control external devices (wheelchairs, computers, etc.).

Methodology—Three-dimensional arrays of electrodes are being micromachined from silicon. The electrodes in the arrays are designed to penetrate into the visual cortex and will either stimulate or record from neurons which are located 1.5 mm deep within the cortex. The arrays are evaluated with implantations in animals.

Results—We are presently building arrays which contain 100 electrodes, each of which is 1.5 mm in length, and tapers from about 80 microns at its base to a sharpened and metalized tip. The electrodes project from a silicon/glass composite base which is 4 mm × 4 mm × 0.12 mm thick. When implanted in the visual cortex of animals, we have been able to

record single-unit, visually evoked neural activity for a 6-month period.

Future Plans—We are currently developing demultiplexing circuitry which will be "solder-bumped" onto the rear surface of the electrode array. This will allow complete electrical access to all 100 electrodes in the array, with only five lead wires. These arrays will be chronically implanted in the visual and/or auditory cortex of animals which have been trained to respond to visual or auditory stimuli.

Recent Publications Resulting from This Research

A Silicon Based Three Dimensional Neural Interface: Manufacturing Processes for an Intracortical Electrode Array. Campbell PK et al., IEEE Trans Biomed Eng, 38:758-768, 1991.

A Glass/Silicon Composite Intracortical Electrode Array. Jones KE, Campbell PK, Normann RA, Ann Bioeng (in press).

A Method for Pneumatically Inserting an Array of Penetrating Electrodes into Cortical Tissue: Dynamic Considerations. Rousche PK, Normann RA, Ann Bioeng (in press).

Simulation of a Phosphene-Based Visual Field: Visual Acuity in a Pixelized Vision System. Cha K, Horch K, Normann RA, Ann Bioeng (in press).

[104] Force-EMG Relationship During Fatigue of Paralyzed Muscles Under FES

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Sponsor: The Segal Foundation; The Walter and Sandra Kaye Research Fund

Purpose—The purpose of this study is to relate the force of the fatiguing muscle during functional electrical stimulation (FES) activation, to its electromyographic (EMG) activity. The muscle studied is the quadriceps of paraplegic patients, in tetanic surface stimulation.

Methodology—When electrically stimulated, the paralyzed muscles of the lower limbs of spastic

paraplegic patients are isolated from voluntary control. If the only non-zero muscle forces are those of the actually activated muscles, the system mechanically analyzed can become determinate, allowing the transformation from joint torque to the forces acting in the individual muscles. This has indeed been done by this group for the continuous and noninvasive calculation of the quadriceps mus-

cle force, from externally measured data, using a specially constructed apparatus. Surface EMG was simultaneously recorded. A stimulus artifact suppressor was designed and constructed to allow detection of the compound muscle action potential (CMAP) of the activated muscle. The suppressor output is connected to the input of a DC amplifier and designed to work with any constant-current stimulator, without any wiring connection to the stimulator.

Results—The peak-to-peak EMG amplitude was found to decrease in the course of fatigue, in parallel with the muscle force. The relation between the two quantities was approximated by a power curve giving, for all of the cases studied, correlation coefficients higher than 0.80. It was also noted that force bursts resulting from strong spastic activity in

one of the patients were accompanied by parallel increases in the peak-to-peak amplitude of the EMG, following the same above-mentioned relation.

Future Plans—The myoelectric activity of stimulated muscles is a potentially important factor in expressing the time dependent response of the muscle to its activation and its correlation to the resulting force developed. We intend to further study the extent of the present findings under differing stimulating conditions.

Recent Publications Resulting from This Research

The Time-Dependent Output of Paraplegics' Quadriceps Muscles Activated by FES. Levy M, et al., in *Advances in External Control of Human Extremities*, D. Popovic (Ed.). Belgrade, Yugoslavia: Popovic, Nauka, 555-569, 1990.

[105] A Model of Recovery Following Fatigue of Paralyzed Muscle Under Intermittent FES

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Sponsor: *The Segal Foundation; The Walter and Sandra Kaye Research Fund*

Purpose—Fatigue of the stimulated quadriceps muscle has been studied metabolically by using ^{13}P magnetic resonance spectroscopy (MRS) in conjunction with the measurement of muscle force, during stimulation of paraplegics. High energy compounds, including phosphocreatine (P_{cr}), inorganic phosphate (P_i), and the derived intracellular pH were shown to vary as a result of fatigue. Recovery of the muscle after stimulation was studied using the very same parameters, which undergo, in this phase, a reverse change toward their rest value. The objective of the present study is to propose a mathematical model of fatigue and recovery as a result of intermittent electrical stimulation.

Methodology—The proposed fatigue-recovery model is based upon three sets of experimental results that describe the pH status in the quadriceps muscle when it is subjected to functional electrical stimulation. The first set contained the pH level of the stimulated muscle when it was stimulated maximally during 3 minutes. The second set contained

the pH level recorded at various stages of a 40-minute recovery phase. The third set describes the relationship between the pH level obtained during the stimulation phase and the tendon force trajectory derived from the recorded force at the ankle.

The fatigue-recovery model allows the transition from the "fatiguing phase" to the recovery phase as soon as the stimulation terminates, and vice versa. The fatigue-recovery model was incorporated with a Huxley-type muscle model describing the dynamics of the muscle.

Results—Two ordinary differential equations governing the musculotendon dynamics and the dynamics of the activation were solved simultaneously and records of the force trajectory during intermittent stimulations were obtained. Improved sets of the fatigue-recovery model parameters were obtained using numerical trials. Finally, sensitivity analysis of the results was conducted to perturbations of some estimated muscle-specific parameters.

Future Plans—It is planned to complete the analysis for force prediction at varying times of activation/recovery, as well as to extend the model

for the inclusion of the activation level as an additional parameter.

[106] Analysis of Fatigue of Paralyzed Muscles Under FES: A Musculotendon Model

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Sponsor: *The Segal Foundation; The Walter and Sandra Kaye Research Fund*

Purpose—In a previous work, we studied the mechanical and metabolic profiles of fatigue of the paralyzed quadriceps muscle of paraplegic patients under activation by FES. The metabolic state of the muscle during stimulation of paraplegic patients was monitored, simultaneously with the decaying force, by using ^{31}P magnetic resonance spectroscopy (MRS). The purpose of the present work was to develop a musculotendon model which incorporates fatigue to enable prediction of the force output during continuous electrical stimulation.

Methodology—The model developed consists of five elements including the tendon, the parallel elastic, contractile and damper muscle elements, as well as the muscle mass. The mechanism of the contractile element is based upon the length-tension and the velocity-tension curves, the activation trajectory and the experimentally obtained relationship between the decaying force and the increasing intracellular pH. This latter parameter was calculated from the chemical shift between the inorganic phosphor (P_i) and the phosphocreatine (P_{cr}), both obtained from the MRS curves.

In the equations obtained, three sets of parameters are being used: 1) general muscle parameters, associated with the length-tension curves of tendon, fascia and muscle, and the velocity-tension curve of the contractile element; 2) specific anthropometric parameters of the muscle; and, 3) fatigue parameters

which, as stated above, were obtained from our previously recorded experimental data.

Results—The model solution provides the force-decaying profiles, which were compared to those obtained experimentally. Specifically, the parameters yielding the best fit between the model and the experimental results were indicated. In addition, two muscle non-specific parameters, namely the muscle stress parameter, and the parameter representing the ratio between the muscle's slack length and its length *in vivo* at various knee angles, were estimated using the model. The muscle stress parameter was found to be between 60 and 64 N/cm^2 and the length ratio was 0.952, 0.935, 0.920, and 0.901 for the 0-degree, 30-degree, 60-degree, and 90-degree knee angle, respectively. Finally, a sensitivity analysis was conducted of the model to perturbations of these two estimated parameters.

Future Plans—It is planned to extend the model developed for the inclusion of the activation level as an additional parameter. For this purpose our previous work on muscle recruitment will be used.

Recent Publications Resulting from This Research

Recruitment, Force and Fatigue Characteristics of Quadriceps Muscles of Paraplegics Isometrically Activated by Surface Functional Stimulation. Levy M, Mizrahi J, Susak Z, J Biomed Eng 12:150-156, 1990.

[107] Modeling and Identification of Electrically Stimulated Muscle

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Sponsor: *Whitaker Foundation*

Purpose—In this project we are using animal preparations and human subject experiments to develop better models of electrically stimulated muscle. In particular, we are interested in how stimulated muscle force varies with stimulation activation, muscle length, muscle velocity, and muscle fatigue. A secondary goal is to develop rapid identification procedures for parameterizing the muscle models. Our goal is to use these models in designing controllers for FES systems which restore gait and grasp.

Progress—We have developed a novel means for identifying the isometric recruitment curve of electrically stimulated muscle in a series of animal experiments. This new method is a factor of 10 faster and provides more resolution than traditional techniques. Knowledge of the isometric recruitment curve is crucial in designing effective, open- or

closed-loop controllers for FES systems. We have also developed means to simultaneously identify the muscle force-length and force-velocity properties using nonlinear system identification methods. These methods were tested both in simulation and in animal experiments.

Future Plans—We are now in the process of transferring the animal model results to verify that the identification methods work for human surface stimulation. This is the first step in deriving practical results from our research.

Recent Publications Resulting from This Research

Muscle Model Identification in Neural Prosthesis Systems. Durfee W, in *Neuroprostheses: Replacing Motor Function After Disease or Disability*, R. Stein, H. Peckham (Eds.). Oxford University Press, 1992.

[108] Muscle Stimulation Strategies for High Contact Density Microstimulation Electrodes

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Sponsor: *Whitaker Health Science Fund*

Purpose—There is a striking contrast between the normal, physiologic activation of muscle by the central nervous system (CNS) and activation of a muscle by functional electrical stimulation (FES). Artificially-induced contractions fatigue rapidly, are difficult to modulate for fine control, and demonstrate gross variation over short time-scales. One of the causes for this difference is the neural interface through which the muscles are activated. The CNS has access to the motor neuron pool of hundreds or thousands of motor units per muscle which it modulates both by recruitment and by timing sequences to produce smooth, low-fatiguing contractions for finely controlled motion. In contrast, artificial stimulation is generally achieved with a

single, gross electrode either wrapped around the peripheral nerve or applied over the surface of the muscle. Here, all muscle fibers are activated synchronously at high, fatiguing, stimulation frequencies to avoid muscle force ripple, and with almost no control over individual motor units, resulting in an undesirable large-to-small motor unit recruitment order.

Recent advances in VLSI technology have led to the miniaturization of electronic components and opens the possibility of designing new neural stimulation interfaces which can contain hundreds or even thousands of electrode contacts, each of which could uniquely activate one or a few motor units. The goal of the research proposed here is not to

develop this electrode technology, but rather to determine how these future, high-contact density, nerve stimulation electrodes should be used to effectively recruit muscle activation in FES applications.

Progress—During the past year we have developed an acute animal model preparation where multiple axons of the rat sciatic nerve are stimulated and isometric force is measured in the triceps surae. Our relatively crude neural interface consists of three arrays each with five standard tungsten wire microelectrodes. Both single-motor unit and whole muscle force is measured by a commercial, wide dynamic range force sensor.

Future Plans—Work to improve the preparation is ongoing. When complete, we will commence experiments with the objectives of: 1) comparing stimulation algorithms; and, 2) developing advanced identification methods for determining the properties of the motor unit connect to each electrode channel.

Recent Publications Resulting from This Research

Microstimulation Using High Contact Density Electrodes. Huang S, Masters thesis, Massachusetts Institute of Technology, 1991.

B. Upper Limb Applications

[109] Tactile Transducers for Closed-Loop FNS of Upper Extremities: A Pilot Study

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Sponsor: VA Rehabilitation Research and Development Service (Pilot Project #B89-10AP)

Purpose—The goal of this pilot project is to quantify the performance of sensors for detecting location, magnitude, and vector of pinch and slippage forces on the fingers. Ultimately, arrays of sensors, most likely assembled from several different types, will provide feedback to a functional neuromuscular system (FNS) controller, so as to relieve the user of the burden of conscious regulation of grip strength. An additional application might be in improvement of clinical assessment of tactile sensitivity.

Since most touch sensors have been developed for robotic applications, they have not been compared directly with normal and impaired human sensory capabilities. Clinical techniques for assessing tactile perception have not heretofore been applied to sensory transducer arrays, but offer an approach to making this comparison. Since it is not known which of the qualitative clinical tests will provide the best comparison, they will be supplemented by a battery of more quantitative bench-top tests of transducer function.

Methodology—Silicon, resistive, capacitive, optical, hydrogel, and Hall effect sensors are obtained and properties of isolated sensors are measured.

Individual sensors are assembled into arrays sized and positioned to fit on a fingertip or palmar surface; arrays may include more than one type of sensor. Arrays are tested using clinical assessment tools such as the Semmes-Weinstein, static and dynamic two-point discrimination, and texture identification, for comparison with normal and minimal human sensation. The arrays are tested on a mechanical simulated "finger" equipped with actuators for exerting known forces against a fixed baseplate, with or without an interposed object to be gripped, using measures of perpendicular force summation, edge detection, object compressibility, object shape discrimination (tactile gnosis), and texture discrimination at known force. Results will be analyzed by normalization against the best performance on a given test and summing weighted normalized scores to arrive at a single figure-of-merit.

Using the same simulated finger fixture, the ability of sensor arrays to detect slippage under standardized uniform conditions are determined. The finger fixture is operated in a closed-loop mode to determine the effect of response time and resolution of sensor arrays on stability of force control, using standard techniques of servomechanism theory.

Results—A four-times scale model simulating the distal phalange of the finger has been made and

shown to provide positional information on a computer display while applying radial force to a pressure-sensitive resistor tactile sensor. Normal-size fingertip models are under construction. If one or more combinations of sensors provide adequate feedback, further research will be undertaken to integrate them with positional sensors, control hardware and software, and FNS stimulating electrodes, preparatory to clinical trial.

[110] Functional Neuromuscular Systems for Upper Extremity Control

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Sponsor: VA Rehabilitation Research and Development Service (Project #B011-4RA)

Purpose—The objective of this work is to develop and evaluate clinical systems employing functional neuromuscular stimulation (FNS) to provide controlled hand motion in C5 and C6 quadriplegics.

Progress/Methodology—Functional electrical stimulation hardware has been developed to provide two grasps: palmar prehension/release and lateral prehension/release. Subjects provided with FNS systems are evaluated for changes of function arising from use of the system using three standardized tests. Patient portable stimulation devices have been developed to supply electrical stimulation to the paralyzed muscles over percutaneously implanted electrodes or an implanted stimulator system. The position of the subject's opposite shoulder regulates the stimuli that are delivered by the device. Clinical evaluation of stimulation system effectiveness is monitored by functional assessment tests.

Results—Subjects using the stimulation devices have demonstrated the ability to perform active grasp/release tasks (using utensils, books, writing instruments, phone, cups, etc.); integrated tasks (pouring, washing, diskette handling, brushing teeth); and sometimes, advanced tasks (e.g., threading a needle, self-catheterization). Retrospective analysis was performed on the ability of quadriplegic patients to complete activities of daily living (ADL) with and without the use of the portable

hand neuroprosthesis. Twenty-two quadriplegic patients were studied: 15 at the C5 level, and 76 at the C6 level. Five of the patients are present neuroprosthesis users.

Results of the study showed that more tasks could be performed successfully when the neuroprosthesis was used. The median success rate across the ten activities that were tested was 89% with a hand neuroprosthesis, but only 49% without the hand neuroprosthesis. The results also suggest that C5 quadriplegic patients benefit more from the use of the hand neuroprosthesis than do C6 patients.

Three patients have been implanted with 8-channel implanted receiver-stimulators. One subject who has been implanted for 5 years continues to use the system on a daily basis for ADL such as eating, grooming, writing, etc. The implanted unit has been functional for 3 years, and the electrodes for the entire 5-year period.

Following approval from the Food and Drug Administration for continued evaluation of this device under an Investigational Device Exemption, two other implantable systems have been installed in human subjects. These two patients have been implanted for a relatively short period; thus, extensive follow-up evaluation is not available.

Twenty implantable devices (BioControl Technology, Inc., Indiana, PA), have been received and will be utilized in additional patients in our program. We have also continued to identify more

subjects who would be participants in this program, and those subjects are presently being evaluated with surface or percutaneous electrode systems.

Individuals with high-level spinal cord injury are provided with functional restoration of ADL with FNS neuroprosthesis. This system utilizes an implanted multichannel stimulator and tendon transfer procedures which have been developed for restoring hand function. The subjects can obtain grasp and release without using an additional orthosis, with the exception that sometimes a wrist/hand is utilized to stabilize the wrist in some subjects. Statistical studies demonstrated that a significant enhancement function was provided to individuals with the FNS neuroprosthesis.

Future Plans—Future research is focused on implementation and evaluation of additional implantable systems for upper extremity control. In this project, five subjects will be studied for a 2-year follow-up period to determine the safety and efficacy of the implantable system in outpatient usage. These subjects will be closely followed to determine the effectiveness of the system using both quantitative and qualitative techniques.

Recent Publications Resulting from This Research

Functional Evaluation of Quadriplegic Patients Using a Hand Neuroprosthesis. Wijman CAC, et al., Arch Phys Med Rehabil 71:1053-1057, 1990.

[111] Prevention of Shoulder Subluxation in Stroke Patients Using FES: A Pilot Study

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Sponsor: VA Rehabilitation Research and Development Service (Pilot Project #B90-86AP)

Purpose—The overall goal of this one-year pilot project is to evaluate objectively the effectiveness of a functional electrical stimulation (FES) treatment program designed to prevent glenohumeral joint stretching and subsequent subluxation in stroke patients.

Progress—A total of 22 patients have participated (10 control and 12 experimental subjects).

Methodology—Recent hemiplegic stroke subjects (within 4 weeks of stroke onset) with shoulder muscle flaccidity are being recruited for this project. Subjects are randomly assigned to a control group and an experimental group. The experimental group undergoes progressive pulsatile FES-induced contractions of two shoulder muscles (the supraspinatus and posterior deltoid muscles) for 10-30 sec on-time, 12-2 sec off-time 5 days a week for 0.5-6.0 hours per day for 6 weeks. A commercially available stimulator utilizing skin surface electrodes is used to produce humeral elevation so that the head of the humerus is pulled into the glenoid cavity. The control group receives standard therapy excluding

any FES application. Both groups use wheelchair arm supports during the 6-week period. Experimental and control subjects are evaluated for joint integrity by radiographs of both involved and uninvolved shoulders prior to and following the 6-week period. Radiographs are taken with the subject in sitting position with the arms hanging freely at the sides. The difference in shoulder subluxation (as measured in mm) between the FES experimental group and the control group will be statistically analyzed using analysis of variance and a 0.05 level for significance.

Preliminary Results—Mean height, weight, and age for control versus experimental subjects tested thus far are 169.4 cm, 71.7 kg, and 67.3, respectively. Shoulder X-ray measurements performed to date indicate a decrease in subluxation for the experimental group following 6 weeks of FES (2.3 to 1.4 mm) compared to an average increase in the control group (7.7 to 9.8 mm). Findings generally suggest a positive effect on prevention of shoulder subluxation with the FES protocol used.

Future Plans/Implications—It appears that this project will produce a relatively low cost system (including protocols and techniques) for the prevention of subluxation in individuals with stroke. The

findings from this study may assist physicians and therapists in the prevention of shoulder subluxation associated with stroke, thereby facilitating the rehabilitation process and reducing treatment costs.

[112] Evaluation of an FNS Orthosis for Quadriplegics

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Sponsor: *Canadian Paraplegic Association; Lyndhurst Hospital, Toronto*

Purpose—The purpose of this study is to clinically evaluate the efficacy of functional neuromuscular stimulation (FNS) hand orthoses in conjunction with Case Western Reserve University, the University of Alberta, Rancho Rehabilitation Engineering Centre, and Shriners Hospital for Crippled Children.

Specific goals are to: 1) implement an FNS system to restore functional hand control in three high-level quadriplegics; 2) determine the ability to minimally operate the FNS system to acquire, move, and release objects using a palmar grasp or lateral grasp; 3) compare functional performance in a variety of activities of daily living (ADL) with and without the FNS system; 4) document compliance to use an FNS system daily and the impact on independent living.

Progress/Methodology—Evaluations are undertaken based on protocols designed by the team from Case Western Reserve University. To determine the ability to minimally operate the system, the Standard Object Test (SOT) is used. This test consists of six tasks in which the subject is asked to acquire, move, and release objects using a palmar grasp or a lateral grasp. The test is administered prior to electrode implantation, and after the initial hand grasp set-up and control training sessions. It is repeated every 3 months as well as after any modifications of the hand grasp. The data collected will be used to determine whether subject performance is consistent over time, both with and without the hand system, and to measure the differences in performance across subjects, with and without the hand system.

To compare ability to perform ADL with and without the system, the Common Object Test (COT) is administered. This test provides a training program in daily tasks integrated with the evaluation of

FNS users. It involves performing a number of selected ADLs (e.g., drinking from a glass, eating with a fork, writing with a pen, etc.). Quality of performance, preference, frequency of activity, method, and independence are evaluated using standard protocols. Testing begins once the system is functioning at an acceptable level for the subject, and after the SOT has been administered. Delays in training and testing have been found to be related to the need to re-implant certain muscle groups at the request of the subject and the team.

Compliance to use the system is evaluated through use of a daily log. The log is initiated once the system is deemed stable. To ensure regular collection of data, phone contact is required. The log will provide a summary of what and how frequently the system is used.

Results—A second subject has been implanted with a total of 26 electrodes in three implantation sessions. Eleven electrodes have become ineffective over time due to breakage or movement relative to the motor point. The remaining electrodes stimulate the major finger and thumb extensors and flexors. One electrode stimulates a wrist extensor as well as the finger extensors, thereby obviating the need for a dorsal wrist splint.

Implications—The electrodes have been programmed to stimulate the muscles in one of two patterns: a lateral prehension pattern and palmar prehension pattern. Although both grasp patterns are functional, it is anticipated that enhanced functionality can be achieved with one further implantation session.

Improvement in the lateral grasp is expected to result from implantation of an electrode to stimulate

adductor pollicis. This will cause the thumb to meet the index finger more proximally than it does now. Another problem with both grasp patterns is that the electrodes that stimulate the flexors of the index finger, primarily flexor digitorum superficialis, tend to overflow to the median nerve and cause the thumb to flex simultaneously. This causes the thumb to miss the index finger in both grasps, requiring the subject to move his thumb into position once the fingers are fully flexed.

The subject is actively using his FNS orthosis on a daily basis. Specifically, he uses the system for securing a grasp on forks, spoons, bottles, etc., and also to secure a pen or pencil for writing. The subject is capable of exerting 1.6 lbf using his lateral grasp and 1.2 lbf using his palmar grasp.

Detailed findings from the SOT and COT evaluations are not available at this time.

[113] Prevention of Secondary Complications in Spinal Cord Injury by Electrical Stimulation: Wrist Extensor Strengthening

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—The objective of this project is to develop an electrical stimulation protocol that will test the effectiveness of FES and biofeedback in obtaining recovery of wrist extensors in the C4-C6 quadriplegic individual. Subjects for this research study are newly spinal cord injured quadriplegic individuals (less than 1 month post-injury), exhibiting manual muscle grade of greater-than-poor-minus for biceps and/or anterior deltoid and manual muscle grade of zero-to-fair for radial wrist extensors. Following intake evaluation and testing, all subjects will receive traditional splinting. The four groups consist of: 1) a control group; 2) a treatment group receiving only biofeedback; 3) a treatment group receiving only electrical stimulation; and, 4) a group receiving both biofeedback and electrical stimulation.

Progress/Methodology—A total of 34 limbs have successfully completed participation in this study. As of July 1991, data from 21 limbs had been analyzed with a two-way analysis of variance

(ANOVA). The dependent variables were: *a*) amplitude of voluntarily produced EMG (i.e., change in microvolt read-outs); *b*) manual muscle test; *c*) evaluation of four graded self-feeding abilities—1) feeds self without use of wrist support (may use utensil); 2) light finger foods (popcorn, chips); 3) moderate finger foods (cookie, 1/2 sandwich); and, 4) drink from 12 oz. soda can.

The following scoring system was used: 0 = patient unable to perform; 1 = patient able to perform, not functional; 2 = patient able to perform functionally in clinic and other settings.

These measurements were taken at the beginning and at the end of the 6-week test period. The results of this statistical analysis as of yet do not show significance for among groups or interaction. It is unfortunate that two individuals in one group dropped out before final data could be collected. Thus, while the number of limbs was actually 34, the missing data points caused others to be omitted because of the need for equal sample sizes in each cell in this design. Data collection is still underway.

[114] Evaluation of Command Channels for Upper Limb Neural Prostheses

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Sponsor: National Institute on Disability and Rehabilitation Research

Purpose—Upper-limb neural prostheses use electrical stimulation to restore grasping function to quadriplegics. The user of such a system must have a signal channel to command the device to open and close the hand. The most common method for generating a command signal is to monitor motion of the contralateral shoulder. This project has the objective of: 1) exploring the limits on performance of upper-limb neural prostheses imposed by the command channel; 2) evaluating novel command channels such as EMG; and, 3) developing assessment and prescription systems for optimizing command channel parameters for a particular user.

The basic approach is through an emulator of an FES hand grasp system. Subjects sit in front of a personal computer and the appropriate command channel being tested is monitored. For example, a sternum-mounted position sensor is used to detect shoulder position. An animation of a grasping task appears on the personal computer display. As the subject moves his real hand, the hand on the screen moves; as the subject manipulates his command channel, the animated hand opens and closes. The subject performs a simulated grasping task by manipulating and moving objects appearing on the screen. Performance is measured by the speed and dexterity with which the task is performed. The advantage of this emulator system is that parameters of the command channel can be changed while keeping the task constant, resulting in efficient cross-comparisons.

Progress/Results—We have conducted a series of tests of shoulder as a command channel in both able-bodied and quadriplegic subjects. The results demonstrate that optimal combination of shoulder command channel parameters such as direction and range vary with individual subjects. This suggests the need for a prescription system which can evaluate each subject and determine the appropriate combination. We have also conducted a preliminary study of EMG as a command channel using able-bodied subjects. Results show that sufficient information transfer is possible with EMG, but at a reduced bandwidth. We have transferred our emulator programs to run on IBM-PC's to simplify the task of technology transfer to other centers, and have created 3-D versions of the simulated tasks.

Future Plans—We are generalizing this research approach to quantify the ability of disabled individuals to control multi-degree-of-freedom devices such as robotic aids, machine tools, and automobiles. In particular, we will look at combined voice and motion command channels for controlling robot manipulators.

Recent Publications Resulting from This Research

Simulator for Evaluating Shoulder Motion as a Command Source for FES Grasp Systems. Durfee W, Mariano T, Zahradnik J, Arch Phys Med Rehabil (in press).

[115] Neural Net Control of FES-Aided Grasp Restoration in Quadriplegics

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Sponsor: NKK Steel Corporation

Purpose—Neural nets show promise for controlling complex, nonlinear systems. By connecting large

numbers of "neuron" elements in interconnected nets, through an iterative learning process, the

controller can converge to a desired system behavior. In this project, we are evaluating the use of neural net controllers in FES-aided quadriplegic grasp restoration devices. In the past, these systems have proven difficult to control, and require a lengthy period of trial and error calibration to determine appropriate stimulation sequences to restore useful grasp. By monitoring hand position and force output, a neural net controller should be able to iterate automatically to a set of acceptable stimulation sequences.

Progress—We conducted a series of experiments to test the ability of neural nets in controlling stimulated thumb motion in a single degree-of-freedom.

The results demonstrated that the weakness of the neural net control strategy is their inability to handle time-varying systems where the time constants of the time variations approach that of the neural net convergence.

Future Plans—We will continue our work in neural net control with an emphasis on solving the time variation problem.

Recent Publications Resulting from This Research

System Identification and Control of the Electrically Stimulated Human Thumb Using Neural Networks. Sekiguchi I, Masters thesis, Massachusetts Institute of Technology, 1991.

C. Lower Limb Applications

[116] Computer Models for Designing FES Systems for Paraplegic Mobility

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Sponsor: VA Rehabilitation Research and Development Service (Project #B289-2RA)

Purpose—The long-term objective is to develop computer tools to assist the rehabilitation team in designing functional electrical stimulation (FES)-control systems so that paraplegics can stand, walk, and perform other lower-extremity motor tasks.

Methodology—The dynamical equations of motion of the body segments for standing, walking, and other motor tasks important to the paraplegic have been generated and implemented on a computer. The musculoskeletal system has also been modeled, including the paths of the lower-extremity musculotendon actuators. The dynamics associated with these actuators have also been computer-coded. An integrated procedure was proposed, and partially implemented, for generating computer code so that musculoskeletal models of multimuscle control of multijoint movement can be constructed (e.g., pedaling, ambulation with a reciprocating gait orthosis [RGO] with or without FES-control). Computer code was generated to display on a workstation the

computer simulations of FES-induced standing, walking, pedaling, and RGO ambulation.

Results—Using computer models and simulations, we have:

- studied the dynamical properties of FES-induced standing and walking;
- found a feedback control for stimulating muscles that ensures stability of standing to large perturbations, and of walking to small perturbations;
- studied standing, and the single- and double-support phases of walking;
- determined the minimum number of muscles and strength needed to effect normal gait;
- studied preliminarily how FES of leg muscles controls pedaling;
- studied preliminarily how the arms and trunk are used by a paraplegic to control RGO walking.

We have also:

- implemented on a graphics workstation an "animated" display of the lower-extremity musculoskeletal system to visualize the simulated standing and walking paraplegic;
- studied how to establish an interactive computer environment for the development of models of neuromusculoskeletal motor tasks.

Implications—Our simulations suggest that FES control automatic feedback controllers can be designed that would stimulate muscles in paraplegics to enable them to stand for a long time without fatigue while they use their hands functionally to manipulate objects. Restoration of normal gait, however, will be much more difficult. We believe

that a combination of FES and orthoses is necessary to be able to restore, in the near future, functional ambulation to paraplegics.

Recent Publications Resulting from This Research

Modeling FES Actuation and Control of Multisegmental Limb Movements. Yamaguchi GT, Zajac FE, in Proceedings of the American Control Conference, San Diego, CA, 2:1048-1053, 1990.

Dynamic Musculoskeletal Models of Human Locomotion: Perspectives on Model Formulation and Control. Yamaguchi GT, Pandey MG, Zajac FE, in Adaptability of Human Gait: Implications for the Control of Locomotion, A. Patla (Ed.). Amsterdam: North-Holland, Adv Psychol 78:205-240, 1991.

Control of Multijoint Lower-Limb Motor Tasks with Functional Neuromuscular Stimulation. Tashman S, Zajac FE, in Neuroprostheses: Replacing Motor Function after Disease and Disability, R.B. Stein, H. Peckham (Eds.). Oxford: Oxford University Press (in press).

[117] Muscle Fiber Recruitment and Strengthening with Electrical Stimulation

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Sponsor: VA Rehabilitation Research and Development Service (Project #B591-RA)

Purpose—The purpose of this project was to determine the factors which influenced the magnitude of torque generated by the human quadriceps muscles during electrical stimulation.

Methodology—Three different types of electrodes were used which varied in material properties and size. Forty subjects were asked to maximally extend their quadriceps muscles and then were stimulated with each electrode type. For each subject, maximum voluntary torque, electrode size, electrode area, electrode impedance, stimulation voltage, stimulation current, and skinfold thickness were measured. These factors were entered into a stepwise regression equation to determine those which most dramatically effected the magnitude of stimulation-induced torque.

Results—It was determined that in spite of the fact that several factors correlated individually with

maximum electrically-induced torque, the factor which most strongly determined torque magnitude was "stimulation efficiency" (defined as stimulation current per unit torque). From these experiments, we concluded that although factors such as electrode size, stimulation current, etc., influenced the magnitude of torque which can be generated using electrical stimulation, the most important factor determining torque magnitude was intrinsic to the individual.

Recent Publications Resulting from This Research

Human Quadriceps Muscle Fatigue at Three Frequencies and Two Duty Cycles Using Electrical Stimulation. Kelly MJ, Lieber RL, In: Transactions of the 37th Annual Meeting of the Orthopedic Research Society, 37:41, 1991.

Factors Influencing Quadriceps Torque Using Transcutaneous Electrical Stimulation. Lieber RL, Kelly J, Phys Ther 71(10):715-723, 1991.

[118] Functional Electrical Stimulation on Spinal Cord Injury Patients

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Purpose—The potential benefits from functional electrical stimulation-induced ergometry of lower extremities (FESIELE) for paraplegic or quadriplegic patients are enhanced functional capabilities of patients, improved cardiovascular fitness and decreased blood cholesterol levels, decreased spasticity, increased bone mineralization with decreased risk of osteopenic bone fractures, prevention of joint contractures, and improvement of peripheral adaptations to exercise including increased muscle mass, energetics, and blood flow. The purpose of this project is to evaluate these possible effects with the ultimate aim of determining the therapeutic value and associated risks of this novel form of rehabilitative therapy.

Progress/Methodology—The population to be studied consists of complete paraplegic and quadriplegic patients who have spasticity. After informed consent is obtained, patients will participate over a period of 12 weeks in an aerobic training program utilizing a computerized bicycle ergometer powered by the lower extremity muscles of the patient, activated through cutaneous electrodes. During the course of this program, the following experimental protocols

will be implemented: (a) Maximal and steady rate VO_2 response; (b) Blood lipids; (c) Muscle fiber density by single fiber EMG and motor unit territory assessment by macro-EMG; (d) Muscle blood flow evaluated by hydrogen clearance; (e) Spasticity estimated by H-reflex, mechanical resistance and EMG response to passive movements, and quantitative clinical examination; (f) Bone mineralization measured by dual photon absorptiometry of the lumbar column and femoral neck and X-ray of the tibia and feet; and, (g) Muscle mass by CT scan of the thigh and calf.

All patients will participate in the aerobic training program and blood lipids study. One group of patients will be enrolled in protocols *a*, *c*, and *d*, and a second group of patients will participate in protocols *e*, *f*, and *g*. A total of 48 training sessions will be performed over a period of 4 months. Evaluations will take place initially, and at the completion of 24 and 48 sessions.

Recent Publications Resulting from This Research

Effect of Functional Electrical Stimulation Using a Computerized Lower Extremity Ergometer on the H-Reflex and Muscle Mass in the Legs of Paralyzed Subjects. Scremin AME, et al., in Proceedings of the American Paraplegia Society, 1990.

[119] FES-Aided Paraplegic Gait Using a Controlled-Brake Orthosis

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Purpose—Restoration of gait to paraplegics using functional electrical stimulation (FES) is a challenging problem. A crucial difficulty is controlling the FES system for stability and smooth gait. One means of improving walking function using surface stimulation is to add a mechanical orthosis in

combination with FES. Based on the preliminary work of our group, we are addressing the problem of designing a functional FES-aided gait system using surface stimulation by testing a hybrid stimulation/orthosis system. The orthosis contains controllable friction brakes at the joints. The pur-

pose of the brake is to shift the burden of control in a gait trajectory from controlling the stimulated muscles and spastic reflexes to controlling the brake, a well-behaved mechanical element. To evaluate brake designs and performance, we are quantitatively testing and comparing the ability of SCI paraplegics to achieve FES-aided gait both with and without the brace. The assessment includes kinematic, dynamic, and metabolic variables.

Progress—Pilot studies based on stimulation of able-bodied subjects to control the knee joint demonstrated the utility of the controlled-brake approach. By combining fine control of the brake with gross control of muscle stimulation, performance on position tracking tasks was greatly improved over both open- and closed-loop control schemes which used stimulation alone. We have completed a computer-controlled, 8-channel stimulator and have be-

gun clinical experiments at the West Roxbury VA Medical Center using ambulating paraplegics. To date we have implemented the standard 4-channel flexor withdrawal FES-aided paraplegic gait in a single subject who is T10 motor complete. We are beginning an FES-aided strengthening program based on the TTI bicycle ergometer. Preliminary designs have also been completed for a laboratory-based orthosis incorporating controllable brakes at the joints.

Future Plans—In the next year we will fabricate the orthosis and conduct gait experiments with SCI individuals at the West Roxbury VAMC.

Recent Publications Resulting from This Research

Open-Loop Position Control of the Knee Joint Using Electrical Stimulation of the Quadriceps and Hamstrings. Hausdorff J, Durfee W, *Med Biol Eng Comp* 29:269-280, 1991.

[120] Functional Tasks Restored in Paralyzed Man Using Electronic Orthotics: FNS Walking in Paraplegics

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Sponsor: VA Rehabilitation Research and Development Service (Project #B193-4RA)

Purpose—The long-term goal of this study is to develop practical functional neuromuscular stimulation (FNS) to restore: 1) the standing function and transfer capabilities in high-level incomplete spinal cord injury individuals; and, 2) standing, walking, and climbing stairs in paraplegics. Our objective is to develop current percutaneous FNS systems into implantable, reliable, cosmetic, self-adjusting devices which will provide paralyzed people with these functions in the home and workplace.

Progress/Methodology—*Percutaneous electrode experience.* After several earlier electrode designs were found to be short-lived, we developed a compound helix electrode, connected to a percutaneous lead, for chronic muscular stimulation. This electrode is implanted without a surgical incision by probing the target muscle with a 26-gauge needle and then inserting the electrode to the motor point through a 15-gauge cannula. Postimplantation electrodes are monitored and removed if there is: 1) a persistent

infection or rejection reaction; 2) an increase in impedance indicating breakage of the electrode or lead; or, 3) an adverse change in muscle response to electrical stimulation (e.g., decrease in muscle force, pain during stimulation, stimulation of unwanted muscles).

The compound helix design has been used for 2 years. Forty-five electrodes have been implanted in the ankle flexor/extensors (soleus, gastrocnemius, tibialis anterior muscles) with 80% surviving; 215 in the hip flexors/adductors/abductors (quadriceps, sartorius, tensor fascia latae, gracilis, adductor longus, posterior adductor, gluteus maximus, gluteus minimus, and gluteus medius muscles) with 68% surviving; 82 in the hamstring muscles with 55% surviving; and 37 near spinal roots to stimulate the quadratus lumborum, erector spinae, and iliopsoas muscles with 37% surviving.

Development of open-loop systems for paraplegics. This study currently involves seven paraplegic subjects. All can stand using their FES systems. Five

can walk and the remaining four can climb stairs. One incomplete quadriplegic subject can also stand up.

Preliminary Results—We are in the process of collecting data with our Motion Analysis System to gain quantitative understanding of kinematics and kinetics of gait and use thereof, as the basis for open-loop stimulation pattern modification. The preliminary results show excessive hip flexion and knee extension moments at the heel strike as compared to normal. Plantar flexion moments during push-off are half of normal.

A major deviation in joint angles as compared to normal is observed at the knee during early stance. In paraplegic gait, the knee remains hyperextended even without activation of quadriceps muscles.

The muscle joint moments in our paraplegic subjects fall short in hip abduction and ankle plantar flexion as compared to those required for normal walking predicted with simulation by others.

Both of these deficiencies can be supplemented by walking aids.

Over a 10-year period, we have evaluated a portable percutaneous FNS system in 15 paraplegics with complete neurological injuries and one incomplete quadriplegic. The FNS system provided standing capability for all subjects and nine paraplegics were able to walk.

Recent Publications Resulting from This Research

A Double Helix Electrode for Functional Electrical Stimulation. Scheiner A, Marsolais EB, in Proceedings of the 13th Annual RESNA Conference, Washington, DC, 373-374, 1990.

Feedback Control of Coronal Plane Hip Angle in Paraplegic Subjects Using Functional Neuromuscular Stimulation. Abbas JJ, Chizeck HJ, IEEE Trans Biomed Eng 38(7):687-689, 1991.

Recursive Parameter Identification of Constrained Systems: An Application to Electrically Stimulated Muscle. Chia TL, Chow PC, Chizeck HJ, IEEE Trans Biomed Eng 38(5):429-442, 1991.

Orthoses and Electrical Stimulation for Walking in Complete Paraplegia. Marsolais EB, et al., J Neurol Rehabil (in press).

[121] Functional Tasks Restored in Paralyzed Man Using Electronic Orthotics: Implant Devices for Lower Extremity FNS Systems

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Purpose—The purpose of this research was to develop intramuscular electrodes to be used with an implantable stimulator.

Progress/Results—The double helix electrode developed for skeletal muscle stimulation and designed to be implanted without surgical incision has been evaluated. Four hundred and forty-six of these electrodes were implanted in a 28-month period in 15 paraplegic and hemiplegic human subjects. Thirty-six different muscle groups (18 bilaterally) were instrumented in the trunk and lower extremities. Three hundred and nine electrodes, or 70%, continue to produce strong, stable muscle contractions enabling paraplegic subjects to walk up to 2,000 meters in a single trial, climb and descend stairs, and take sideward and backward steps.

Electrode longevity varied with the area of

implant with the best results being in the tibialis, gastrocnemius, quadriceps, and gluteal muscles and the worst results being in the trunk (erector spinae and iliopsoas spinal root stimulation) and hamstring areas. The main causes for electrode failure have been: 1) inability to locate and properly place the electrode in a suitable site for stimulation during surgery (8%—36); 2) unwanted changes in muscle response to stimulation (10%—45—mostly occurring during the first 6-weeks postimplant); 3) increase in electrode impedance (10%—48—assumed breakage, mostly occurring after the 12th week postimplant); and, 4) intolerable pain during stimulation (2%—8). Few adverse physiologic reactions were seen.

Future Plans—An implantable stimulating 'subcutaneous' electrode clearly designed to be placed

superficial to the subfascial layer overlaying the motor point of a paralyzed muscle has been conceived and tested in human subjects. This unique electrode design is easy to implant (requiring only a 1.2 mm incision), relatively noninvasive (placed just below the skin), and mechanically stable after implantation, producing repeatable muscle response. The electrode is constructed of platinum foil placed between two layers of dacron-reinforced silastic sheeting. Stress relief in the lead is provided using a 2 cm double helix section at the lead/electrode

junction. It is able to pass relatively large amounts of current, up to 100 mA at 250 μ sec pulse-width, safely to body tissue. The muscle recruitment properties of this design are similar to surface electrodes with subcutaneous electrodes using slightly less charge per stimulating pulse. This design is especially suited for use when a 'large' stimulating electric field is needed. For standing or walking of paraplegics in the lower extremity, this would be especially useful to stimulate the hamstring, quadriceps, and erector spinae muscles.

[122] Functional Tasks Restored in Paralyzed Man Using Electronic Orthotics: Development of Stimulation Control Methods

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Purpose—The purpose of this segment of the study was to demonstrate the feasibility of using percutaneous techniques to obtain laboratory-based ambulatory functions in subjects with complete paraplegia.

Progress/Methodology—We have implanted most lower extremity muscles, and developed exercise protocols to condition them. We have achieved standing in all 15 subjects to date with at least one-hand support, except for brief periods, and we have attained locomotion in 66% (10) of thoracic-level paraplegic subjects. Several have been able to climb and descend one flight of steps with one crutch and one or two railings. However, without knee, hip, and trunk bracing, electrical stimulation is required at all times to maintain standing while performing tasks with the hands. Without automatic adjustment of stimulation and without bracing, the physiological effort (upper body) required to maintain standing while performing functional one- and two-handed tasks, and to attain locomotion, is unacceptably high.

To address these problems, algorithms and computer software for the feedback control of electrical stimulation have been developed and are based on hierarchical structure. In past and current work, these algorithms without knee, hip, or trunk bracing have been applied separately to the knee and mediolateral hip during standing using co-stimula-

tion of groups of muscles. Characterization of disturbance response during functional neuromuscular stimulated (FNS) standing has also been studied. The use of feedback control of knee angle is being evaluated during the support phase of gait.

Results—Evaluation of two different feedback controller configurations for hip and trunk in the coronal plane have been undertaken. Feedback control of coronal plane hip angle was reduced in rms error and steady-state error, and calculated with respect to steady-state as compared to open loop. A set of subjective ratings by clinicians indicated that these control system design criteria alone may not be appropriate indicators of the desired performance characteristics. Control of both hip and trunk angles using independent controllers suggested that coordination is needed for adequate maintenance of posture in the presence of disturbances.

Feedback control of electrical stimulation to the muscles of the lower extremity, based upon knee angle measurements, was used to maintain standing despite disturbances. A pulse width/stimulus period (PW/SP) controller was used. The controller algorithm provided knee recovery to extension after repeated flexion disturbances were applied to the knees. The time course of several biomechanical responses was analyzed for each flexion disturbance and a repeatable pattern of events was found to exist. The subject's perception of his supporting

effort was related to the actual amount of effort exerted during the disturbance trials.

Current research on the use of feedback controllers during the supporting phases of gait is focusing on the need for predictive capabilities in these joint controllers to account for the delays of stimulation and computation.

Future Plans—Two approaches to this problem are being investigated. One of these (described in a separate progress report), involved the development of artificial neural net-based systems to provide this control. A second approach, involving fuzzy logic implementation, on-line stimulation pattern modifications, and controller tuning, is the focus of a new project.

A full evaluation of the ability of paraplegic individuals to perform functional tasks with the

upper extremities with combined feedback control of the ankles, knees, and mediolateral hip remains to be done.

Recent Publications Resulting from This Research

Characterization of Paraplegic Disturbance Response During FNS Standing. Moynahan M, Chizeck HJ, IEEE Trans Biomed Eng 38(5):429-442, 1991.

Feedback Control of Coronal Plane Hip Angle in Paraplegic Subjects Using Functional Neuromuscular Stimulation. Abbas J, Chizeck HJ, IEEE Trans Biomed Eng 38(7):687-698, 1991.

Feedback Control of Electrically Stimulated Muscle Using Simultaneous Pulse Width and Stimulus Period Modulation. Chizeck HJ, et al., IEEE Trans Biomed Eng 38(12):1224-1234, 1991.

Adaptive and Nonlinear Control Methods for Neuroprostheses. Chizeck HJ, in Neuroprostheses: Replacing Motor Function After Disease or Disability, R. Stein, P.H. Peckham, D. Popovic (Eds.). New York: Oxford University Press (in press).

[123] Functional Tasks Restored in Paralyzed Man Using Electronic Orthotics: FNS Systems for Gait Assist and Motor Retraining in Stroke and Head Injury Subjects

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Sponsor: VA Rehabilitation Research and Development Service (Project #B193-4RA)

Purpose—The long-term goal of this work is to determine the efficacy of using functional neuromuscular stimulation (FNS) in rehabilitation of paretic and paralyzed head-injured and stroke patients. The two hypotheses are: 1) FNS used for motor retraining in paretic patients will improve voluntary motor control, speed, and cosmesis of gait, and safety of walking, stair-climbing, and other functional maneuvers; and, 2) FNS used as an orthotic device for the paralyzed patient will improve gait to a more functional level.

Progress/Results—Systems using intramuscular electrodes with percutaneous leads have been developed and tested in paraplegic and paretic patients who demonstrated significantly improved function. We found improved gait and endurance for a mildly impaired subject, and a severely involved (12-months poststroke) nonambulator, and we found that the percutaneous FNS system resulted in the ability to ambulate 80 feet numerous times, using a hemi-walker.

Restoration of function for head injury diagnosis. Case study videotape of a head-injured subject documented a progressive 2-year improvement in motor function, ambulatory status, and functional activities of daily living. Voluntary muscle function improved for hip flexors, hip and knee extensors, and ankle dorsiflexors. Voluntary functional improvements included walking 50 feet with standard canes without FNS. Using the FNS, ambulatory status improved from wheelchair mobility to ambulation with one cane and stand-by assist for distances of over one-quarter of a mile. Other improved capabilities included stair ascension and descension without FNS. Because of the possible confounding variable of spontaneous recovery, one case study cannot conclusively determine the efficacy of FNS for treating head injury motor deficits. However, improvements in motor deficits occurred in this case, in close temporal relationship to specific FNS treatment, strongly suggesting a cause and effect relationship.

Restoration of function for hemiplegics. Case study video data show that with FNS, functional status improvement was achieved for 100% of the four hemiplegic subjects treated. Functional improvement was from wheelchair mobility to ambulatory status of various levels.

FNS and movement retraining for hemiparetics. Case study videotape and kinematic data indicated gait pattern improvement following a combination of treatment with FNS-driven, FNS-assisted, and voluntary movement retraining techniques. During slow cadence walking (56 steps/min), kinematic data documented improvement to normal for swing-knee flexion, and knee extension prior to heel strike. Motor retraining for moderate and fast speed walking was also studied and kinematically quantified. That data is undergoing analysis. A prototype snap connector for percutaneous leads has been developed and tested for those with visual and upper extremity motor dysfunction. The design has been successfully used by one very disabled subject.

Future Plans—Ongoing and future studies will

require controls for spontaneous recovery, a larger sample size in order to generalize results, and simplification of the system for clinical use. Outcome measures used to identify benefits will be gait analysis, muscle function evaluation, testing of functional maneuvers, and evaluation of the ease of use of the FNS system by patients and therapists. This research will yield new information regarding the benefits of specific FNS-driven and assisted exercise and decision-making criteria for designing rehabilitation FNS exercise for paretic patients. In addition, this work will yield a patient profile of those paralyzed patients who will benefit functionally from the FNS system as an orthotic device.

Recent Publications Resulting from This Research

- Stroke Gait Correction with Multi-Channel FNS. Marsolais EB, et al., in Proceedings of the 36th Annual Meeting of the Orthopaedic Research Society, New Orleans, 553, 1990.
Improved Voluntary Gait Pattern Post Stroke, Following Treatment with the Multi-Channel, Intramuscular, Microprocessor-Based FNS System. Jacobs JL, et al., in Proceedings of the 14th Annual RESNA Conference, Kansas City, MO, 283-285, 1991.

[124] Functional Tasks Restored in Paralyzed Man Using Electronic Orthotics: A Neural Network Controller for FNS Systems

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Sponsor: VA Rehabilitation Research and Development Service (Project #B193-4RA)

Purpose—This work aims to develop control methods for lower extremity functional neuromuscular stimulation (FNS) systems which will be practical for clinical use. It addresses three major problems with current lower extremity FNS systems: 1) the stimulation parameters must be customized for each individual; 2) the stimulation parameters are fixed and thus cannot respond to system changes; and, 3) there is no facility for on-line adjustments to respond to disturbances. Thus, the purpose of this project is to develop a control system for lower extremity FNS systems which provides automated customization of stimulation parameters, on-line adaptation of these parameters to respond to system changes, and feedback control to respond to disturbances.

Methodology—A neural network control system has been designed which consists of two stages: a pattern generator (PG) and an output stage (OS). The PG generates activation trajectories which are selected for a given movement. The design of this stage is based upon neural models of locomotor control. The OS stage acts as an adaptive filter of PG outputs. The adaptive properties of the OS are provided by modifications to standard artificial neural network learning algorithms. Feedback (FB) has also been incorporated into the OS to allow the controller to respond to disturbances.

A series of experiments have been performed on computer-simulated musculoskeletal models in order to evaluate the ability of the control system to automatically customize the stimulation parameters

and to adapt them on-line. The system-to-be-controlled consisted of a model of an agonist-antagonist pair of muscles acting on a single joint. A desired angular trajectory for the joint was a 1 Hz sinusoid with an amplitude of 20 degrees.

The experiments consisted of a training and an evaluation session. During the training session, the FB controller was active and the FF controller was being adapted. Initial FF parameters were set such that initially it provided no input; as adaptation occurred, it learned to provide the appropriate input. This training was done for 20 cycles of movement (20 sec), in which the FF controller was being automatically customized and adapted on-line. In the evaluation session, the FB controller was not active and the FF controller was not being adapted. The rms error value of the tracking error was used to evaluate the control system performance. Thus, the evaluation focused on the ability of the customized FF controller to control the system. This experiment was first performed on a musculoskeletal model with system parameters drawn from the literature. Each of five different system parameters (muscle gain, muscle hysteresis, segment mass, joint stiffness, and joint damping) was varied, one at a time, $\pm 50\%$ in increments of 10%. The same experiment was then performed on each system.

Results/Implications—For each of the systems tested, the customized FF controller resulted in tracking to within an rms error of less than 1.5 degrees, which is less than 4% of the peak-to-peak value of the desired trajectory. These results demonstrate the ability of the control system to customize the FF controller parameters for a given musculoskeletal system. The customization occurs on-line, and therefore also provides on-line adaptation. Thus, this control system has been demonstrated to provide: automated customization, on-line adaptation, and feedback control.

Future Plans—Future work will be directed at: 1) incorporating real-time feedback control into the PG to make timing adjustments to the activation pattern; 2) developing the PG and OS stages to enable them to control multi-degree-of-freedom skeletal systems through a variety of coordinated movements; and, 3) evaluation of the control system in experiments on human subjects.

Recent Publications Resulting from This Research

A Neural Network Controller for Functional Neuromuscular Stimulation Systems. Abbas JJ, Chizeck HJ, in Proceedings of the 13th Annual Conference of the IEEE Engineering in Medicine and Biology Society, Orlando, FL, 1991.

[125] Functional Tasks Restored in Paralyzed Man Using Electronic Orthotics: Feedback Control of the Stance Leg During FNS Gait

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Purpose—The purpose of this study was to develop a feedback controller which would provide improved functional abilities to paraplegic patients by automatically updating the stimulation parameters to selected channels in real-time. In particular, feedback control of the knee angle during weight transfer was employed to improve weight transfer by reducing hyperextension, increasing average walking speed, and reducing the amount of arm support. Weight transfer is the period of time from heelstrike until the majority of the weight of the body is supported on the recently landed leg.

Progress/Methodology—This work was a three-stage study of feedback control of knee angle. The controller was a digital PD controller with setpoint prediction. In the first stage, a mechanical apparatus was designed in computer simulation and then built to be used as a load during controller tuning trials. The apparatus resembled an inverted pendulum. As the leg flexed from full extension, the weights moved forward with the leg and applied an increasing torque to the knee which mimicked the torques experienced during normal weight transfer.

During the second stage, the relationships between the controller parameters and the output measures were documented for sinusoidal knee-angle tracking trials both in computer simulation and in actual experiments. The simulations were performed on a 386 AT compatible computer and the experiments were performed on a supine T-8 complete paraplegic subject in the mechanical apparatus which was designed in stage one. Knee angle was measured by a strain gauge. The controller output was used in conjunction with a pulsewidth map to determine the stimulation pulsewidths to the quadriceps (knee extensors) and the hamstrings (knee flexors).

In the final stage, several of the controllers which performed well during the supine tuning experiments were evaluated and compared to open-loop control during functional neuromuscular stimulated (FNS) gait. The controller again determined the stimulation pulsewidths for the quadriceps and hamstrings, but all other muscle electrodes were stimulated with their previously developed open-loop stimulation patterns.

Results—In the first stage, the pendulum mass and height were chosen so that the knee torque experienced during the sinusoidal knee-angle tracking task was within 1% of the knee torque which is experienced during normal weight transfer over the same knee angle trajectory.

The second stage showed that the size of the sinusoid depended mostly on the derivative gain of

the PD controller, the time delay in tracking depended mostly on the amount of setpoint prediction, and the mean of the sinusoid depended mostly on the pulsewidth map. When the trials were divided into a transient response (cycles 1 to 4) and a steady state response (cycles 5 to 8), RMS errors of 4 degrees and 2 degrees were achieved respectively.

The third stage of experiments showed that the pendulum-tuned controllers had statistically significant reduced hyperextension as compared to open-loop walking. However, these controllers still lacked the characteristic knee flexion immediately after heelstrike which is seen in normal gait. Differences in walking speed and arm forces between the open-loop and closed-loop controllers were not significant.

Future Plans—These experiments are currently being repeated on two additional paraplegic subjects. The effect of initial conditions on controller performance is being investigated. From these results, initial condition bounds for acceptable performance will be specified. These bounds will then become the endpoint goals for the previous phase of gait.

Recent Publications Resulting from This Research

Feedback Control of the Knee Angle During FNS Gait. Willemin DE, Chizeck HJ, in Proceedings of the IEEE/EMBS 13th Annual Conference, Orlando, FL, 1991.
Feedback Control of the Stance Leg in FNS Gait. Willemin DE, Masters thesis, Case Western Reserve University, 1991.

[126] Nonlinear Controllers for FES-Aided Gait

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Sponsor: VA Medical Center; National Institutes of Health

Purpose—One of the difficulties in controlling FES-aided paraplegic gait is that muscles are nonlinear, time-varying actuators. In this project, we are evaluating the effectiveness of advanced nonlinear controllers to control these systems.

Progress—In a series of simulation studies and a preliminary series of human experimentation, we

have implemented adaptive and nonadaptive forms of sliding controllers, a control structure which is well-suited to systems which cannot be modeled precisely. Although the simulations demonstrated that sliding controllers showed great promise, the initial human experimentation, which had the objective of position control of the unloaded shank, proved to be disappointing.

Future Plans—We are continuing the human experimentation and are redesigning our controllers to include a more detailed muscle model.

Recent Publications Resulting from This Research

Control of Standing and Gait Using Electrical Stimulation: Influence of Muscle Model Complexity on Control Strategy. Durfee W, Prog Br Res (in press).

[127] Treatment and Evaluation of Paraplegic Patients Using Surface FES

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Sponsor: Israel Ministry of Defense; The Segal Foundation

Purpose—The purpose of this study is to apply surface functional electrical stimulation (FES) on paraplegic patients for the activation of the paralyzed limbs. Whenever indicated, supported standing and walking are also implemented.

Methodology—A six-channel lightweight portable and computer-controlled stimulator was developed. To enable programming of the various functions, the stimulator was designed to work in a remote control mode hosted by an IBM-PC or compatible computer, in addition to its normally used local mode. The stimulator parameters, including current intensity, stimulus frequency, and pulse width were individually adjustable and programmable for each channel.

In addition, an instrumented walker was designed to serve as a standing/walking support. Various training programs for the activation of paraplegics in the sitting, standing, and walking positions were developed.

The patients treated are also evaluated clinically, biomechanically, and physiologically, to monitor the performance of the activated patients and to optimize stimulation.

Results—Over 20 patients have so far been treated and evaluated. Nineteen of these patients were able

to achieve standing and supported walking for distances of approximately 100 m. Evaluation of the patients included weightbearing, gait analysis, oxygen consumption, heart rate, pulmonary function, urodynamics, and muscle fatigue.

Using magnetic resonance spectroscopy techniques *in vivo*, it has also been possible to monitor recovery of the muscle following fatigue.

Future Plans—Based on accumulated experience, it is planned to improve the stimulator/walker kit for implementation on a wider paraplegic population.

Recent Publications Resulting from This Research

Fatigue of the Quadriceps Muscles of Paraplegics Under FES—In Vivo P-31 NMR Studies. Levy M, et al., in Proceedings of the 29th Annual Science Meeting of the International Medical Society of Paraplegia, Ramat Gan, Israel, 13, 1990.

Recruitment, Force and Fatigue Characteristics of Quadriceps Muscles of Paraplegics, Isometrically Activated by Surface FES. Levy M, Mizrahi J, Susak Z, J Biomed Eng 12:150-156, 1990.

The Time-Dependent Output of Paraplegics' Quadriceps Muscles Activated by FES. Levy M, et al., in Advances in External Control of Human Extremities. B. Dejan (Ed.), Belgrade, Yugoslavia: Popovic, Nauka, 555-570, 1990.

[128] Development of FES-Powered High Performance Walking Orthosis for Paraplegics

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Sponsor: Louisiana State University Board of Regents

Purpose/Methodology—A practical, FES-powered walking orthosis was developed and tested in a group of patients. The system consists of Louisiana State University's Reciprocating Gait Orthosis (RGO) which provides paraplegics with the ability to stand upright with full balance for indefinite periods of time. Locomotion is accomplished by simultaneous stimulation of one quadriceps and the contralateral hamstrings to allow the swing of one leg and simultaneous push-off of the contralateral one. A four-channel reciprocal stimulator triggered by a thumb switch on the walker and powered by a 9V battery was developed and tested. The system is custom made to each patient, and allows FES-powered standing from a chair, as well as walking on ramps. Energy consumption studies reveal its superiority over other systems in Kcal/kg-m and Kcal/kg-min.

Progress/Preliminary Results—Current work focuses on improving the force transmission from one hip to the other, redesigning the hip, knee and ankle joint, and long-term evaluation of patients.

Technology transfer was made to several countries in Europe, Africa, and Australia.

Recent Publications Resulting from This Research

Energy Consumption of Paraplegics Ambulating With the LSU Reciprocating Gait Orthosis Powered by Electrical Stimulation of the Thigh Muscle. Hirokawa S, et al., Arch Phys Med Rehabil 7:687-694, 1990.

Current Status of Walking Orthosis for Thoracic Paraplegics. Solomonow M, et al., Mediguide to Orthopaedic 10:1-8, 1991.

Biomechanics and Physiology of A Practical Walking Orthosis for Paraplegics. Solomonow M, in: Neural Prosthesis: Replacing Motor Function After Disease or Disability. R.B. Stein, H. Peckham, D. Popovic (Eds.). New York: Oxford University Press (in press).

[129] Long-Term Medical Effects of Paraplegic Ambulation with FES-Powered Orthosis

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Sponsor: Louisiana State University

Purpose—The long-term effects of paraplegics ambulating with the aid of muscle stimulation powered orthosis is not known. Short-term evaluation points out that profound changes occur in the physiological and metabolic conditions of the patient. Some of these changes are: improvements in bowel and bladder functions, improved cardiopulmonary condition, reduction in spasticity, possible reversal of osteoporosis, and improved circulation in the lower extremities. The purpose of this project is to evaluate the changes in various physiological functions associated with long-term usage of FES-

powered orthosis (i.e., the LSU Reciprocating Gait Orthosis—RGO II).

Preliminary Results—To date, a comprehensive review of the literature has been conducted and consultation with various medical specialists completed. A report includes all the possible physiological changes that should be anticipated and the state-of-the-art methods for their monitoring/measurement. Files have been constructed with complete follow-up instructions, monitoring, and documentation.

[130] Physiological and Biomechanical Infrastructure for the Design of FES Controller for Agonist-Antagonist Muscles of a Joint

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Sponsor: National Science Foundation

Purpose—Control of a paralyzed limb joint is deficient if functional electrical stimulation (FES) is applied only to the agonist muscles. Electrical stimulation of the antagonist is required to be applied simultaneously in order to increase accuracy and function. The purpose of this project was to develop the biomechanical and physiological infrastructure necessary for the design of a high performance costimulation controller.

Results—We found, from a series of experiments conducted over the last 5 years, that antagonist coactivation is highly variable and responsive to various environmental, mechanical, and anatomical functions. The antagonist coactivation level is variable with respect to the orientation of the gravity

vector, joint velocity, muscle moment arm, agonist force, persons with expertise in a specific motion, as well as ligament stress. More than all, it was determined that electrical stimulation of the agonist only may result in potential significant damage to the joint if applied over a period of time. This should be avoided.

Recent Publications Resulting from This Research

The Effect of Joint Velocity on the Contribution of the Antagonist Musculature to Knee Stability. Hagood S, et al., *Am J Sports Med* 18(2):182-187, 1990.

Anterior Posterior Displacement of the Tibia Elicited by Quadriceps Contraction. Hirokawa S, et al., *Am J Sports Med* (in press). Muscular Co-Contraction and the Control of Knee Stability. Hirokawa S, et al., *J Electromyog Kinesiol* (in press).

[131] Muscular Coactivation and Knee Stability

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Sponsor: National Science Foundation

Purpose—The purpose of this project was to assess the relationship between agonist-antagonist coactivation and stability of the knee and its major ligaments. Applications range from preventing ligamentous damage, to improving therapeutic methods post-ligament damage or corrective surgery, and to prevent knee instability when electrical stimulation is used to restore locomotion to paraplegics.

Results—We found that the antagonist muscle is assuming a significant role in regulating the joint against various external and internal disturbances. This regulatory role, which is observed under various movement conditions, is found to ensure joint stability and prevent undue stress and injury to ligaments.

Recent simulation of coactivation performed on cadaver knees fully confirmed that lack of antagonist coactivation results in significant displacement of the tibia relative to the femur. It is now clear that antagonist coactivation is necessary not only for control of joint motion but also its protection from instability.

Recent Publications Resulting from This Research

The Effect of Joint Velocity on the Contribution of the Antagonist Musculature to Knee Stability. Hagood S, et al., *Am J Sports Med* 18(2):182-187, 1990.

Anterior Posterior Displacement of the Tibia Elicited by Quadriceps Contraction. Hagood S, et al., *Am J Sports Med* (in press).

Muscular Co-Contraction and the Control of Knee Stability. Hirokawa S, et al., *J Electromyog Kinesiol* (in press).

[132] Mobility Restoration

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Sponsor: *University of Twente; Rehabilitation Center Het Roessingh; European CALIES-Project*

Purpose—The purpose of this program is to develop methods and systems for restoration of mobility in paraplegics using hybrid systems. It is a cooperative project of the Departments of Electrical Engineering and Mechanical Engineering, and the Rehabilitation Center "het Roessingh." The objective is to develop methods which may improve hybrid systems for restoration of functions on both a shorter term (5 years), as well as on the longer term. The projects started in 1990 and 1991 in this program are as follows:

1. *Fascicle Selective Nerve Stimulation.* (Project leader: J. Holsheimer). Aim: To develop electrode configurations and stimulation principles for fascicle selective stimulation of nerve for improved control of muscle contraction. Progress: The principle of fascicle selective nerve stimulation has been simulated in a model study and tested in experiments on rats.

2. *Nerve Fiber Selective Stimulation and Sensing.* (Project leader: Wim L.C. Rutten). Aim: To investigate the possibilities to activate and measure the activity of single nerve fibers or small groups of nerve fibers in a fascicle selectively, and to develop multi-electrode configurations for intrafascicular stimulation and sensing. Progress: A one-dimensional multi-electrode has been developed and tested for selectivity. Two- and three-dimensional (3-D) configurations are being developed and tested.

3. *Control of Stimulation for Restoration of Limb Function.* (Project leader: P.H. Veltink). Aim: To develop control strategies for restoration of paraplegic gait using electrical stimulation. Progress: Methods have been developed and are being evaluated for control of cyclical leg movements. The principle is optimal control of minimal muscle fatigue, in combination with adaptive control to compensate time-dependent features in the system, like fatigue. A fatigue study during isometric con-

tractions has been performed.

4. *Biomechanical Modeling of Hybrid Assisted Paraplegic Gait.* (Project leader: Bart Koopman). Aim: To develop 3-D biomechanical models of hybrid-assisted paraplegic gait, in order to optimize the design of the system (orthosis design, stimulation system and control). Progress: A 3-D model of hybrid-assisted paraplegic gait is being developed on the basis of previously developed 3-D models of human gait.

5. *Improved Hybrid System.* (Project leader: H.J. Hermens). Aim: To develop an improved hybrid system for paraplegic gait. Progress: The design of the orthosis has been specified and parts are being tested. Improved activation of hip extensors and flexors with surface stimulation electrodes are being evaluated.

Recent Publications Resulting from This Research

- Anodal Block of Myelinated Nerve Fibers: A Modeling Study. Holsheimer J, van der Heide GG, Struijk JJ, Proceedings of the 12th Annual Conference of the IEEE Engineering in Medicine and Biology Society, Philadelphia, PA, 2236-2237, 1990.
- Multi-Groove Electrode for Fascicle Selective Nerve Stimulation. Koole P, Holsheimer J, Proceedings of the 10th International Symposium on External Control of Human Extremities, Dubrovnik, 307-317, 1990.
- Artificial-Reflex Stimulation for FES-Induced Standing with Minimum Quadriceps Force. Mulder AJ, et al., Med Biol Eng Comput 28:483-488, 1991.
- Sensitivity and Selectivity of Intraneural Stimulation Using a Silicon Electrode Array. Rutten WLC, van Wier H, Put JHM, IEEE Trans Biomed Eng, 192-198, 1991.
- Control of FES-Induced Cyclical Movements of the Lower Leg. Veltink PH, Med Biol Eng Comput (in press).
- Nonlinear Joint Angle Control for Artificial Stimulated Muscle. Veltink PH, et al., IEEE Trans Biomed Eng (in press).
- Selectivity of Intraneural Prosthetic Interfaces for Muscular Control. Rutten WLC, Meier JH, Med Biol Eng Comput (in press).
- Simulation of Multipolar Fibre Selective Neural Stimulation Using Intrafascicular Electrodes. Meier JH, et al., IEEE Trans Biomed Eng (in press).

V. Geriatrics

[133] Use of an Obstacle Course in the Rehabilitation of Elderly Fallers

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Sponsor: VA Rehabilitation Research and Development Service (Project #E641-RA)

Purpose—The purpose of this study is to determine whether a low-cost, functionally-oriented obstacle course may aid in the evaluation and rehabilitation of elderly subjects who fall. The major research questions are: 1) whether performance on the obstacle course can be used to identify and quantify functional mobility and balance impairment, which is often undetected using standard clinical examination techniques; and 2) whether the integration of supervised practice on the individual stations of the obstacle course into an exercise-based balance rehabilitation training program will enhance the therapeutic effectiveness of the program.

Methodology—The obstacle course consists of a series of 12 simulated obstacles which may be commonly encountered in and around the home environment (doorway, stairs, ramps, variable flooring surfaces, walking around and stepping over objects, etc.). Obstacles are designed to challenge different physiologic balance and ambulation strategies. Obstacle course testing is conducted according to a standard protocol. Performance on the obstacle course is videotaped. Videotapes are reviewed by a rater who is blind to subject group assignment. Obstacle course performances are scored according to specific criteria, including type and amount of balance "errors" and time taken to complete the overall course and each individual station.

Community-dwelling ambulatory outpatient veterans, aged 65 or older, with or without a history of one or more falls in the previous 12 months at study entry, are eligible. Subjects are divided into three groups: 1) non-fallers; 2) fallers who are put through a 6-week balance retraining

program including practice on the obstacle course; and, 3) fallers who are put through an otherwise identical 6-week balance retraining program excluding practice on the obstacle course. Subjects also receive clinical assessments by a team (physician, nurse practitioner, physical therapist) which includes their obstacle course performance, demographic data, medical history, neurological examination, muscle strength and flexibility testing. Data are compared among the three groups at baseline, 6-week post-test, and 6-month follow-up. Data analysis will include repeated measures of analysis of variance.

Progress—During the first 5 months of this 12-month study, major activities have focused on construction, modification, and preliminary testing of the obstacle course, instrument revisions, training and reliability testing of staff, subject identification and recruitment, and data collection. A total of 77 subjects have been recruited into the study and have completed their baseline evaluation. Twenty-six of these subjects have completed their post-test evaluations. A total sample of 120 subjects (60 fallers and 60 non-fallers) is anticipated.

Results/Implications—While an insufficient amount of data has been collected to date to permit any detailed analysis, one trend has been observed—overall and individual station qualitative and quantitative differences do exist in obstacle course performance among fallers and non-fallers. This suggests that the obstacle course may have some practical use in the clinical evaluation of elderly subjects with balance and mobility impairment.

[134] Interventions to Improve Dressing Behavior in Cognitively Impaired Veterans

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Sponsor: VA Rehabilitation Research and Development Service (Project #E558-RA)

Purpose—This study examines the difference in the assistance required by subjects in the performance of dressing before and after receiving the clinical intervention of Strategies for Promoting Independence in Dressing (SPID).

Progress/Methodology—We have completed the intervention, analyzed data, written articles, and made presentations on this project.

Data collection has been completed on two nursing home care units at the VA Medical Center, North Little Rock Division. A pretest/posttest design was used in which each subject served as his own control. The major dependent variable was the level of assistance each subject required during dressing as measured by the Beck Dressing Performance Scale (BDPS). Fifteen patients with a diagnosis of dementia were identified and included in the study. The 15 subjects were videotaped during subject/caregiver dressing interaction, twice a week for one week to desensitize the subjects and caregivers to the videotaping procedure. Then, baseline data were collected by videotaping dressing twice a week for another 2 weeks. The clinical intervention SPID consisting of specific environmental, interactional, and cognitive strategies was then taught to caregivers during a 3-week period. The intervention was individualized to the specific abilities and disabilities of each subject. Registered nurses, licensed practical nurses, and nursing assistants implemented the intervention. Intervention data were collected by videotaping caregiver/patient dressing interactions twice a week for 6 weeks. During this intervention period, the investigators gave weekly feedback and encouragement to the caregivers regarding their implementation of SPID.

Feedback and encouragement was then stopped, and post-intervention data were collected twice a week for 2 weeks. Videotaping was stopped for 3 weeks. Then, follow-up data were collected by videotaping caregiver/subject dressing interactions twice a week for one week.

Final Results—Videotapes were randomized, and two trained raters rated the videotapes for caregiver assistance and aggression using the BDPS and the Ryden Aggression Scale. Mean caregiver assistance scores, as measured by the BDPS, decreased from 6.26 (sd = 1.49) at baseline to 4.93 (sd = 1.90) after 6 weeks of intervention. The significance of the apparent improvements in the mean BDPS scores over time was assessed by the paired *t*-test and Wilcoxon signed ranks test. All comparisons were significant at the 0.002 level or better. Mean caregiver assistance scores remained stable during follow-up observations (4.71, sd = 2.05).

We are currently replicating this study with other populations in another study, "Improving Dressing Behavior in Cognitively Impaired Elderly," in which preliminary results also show significance.

Recent Publications Resulting from This Research

Caring for the Cognitively Impaired: Reconceptualizing Disability and Rehabilitation. Heacock P, et al., *J Gerontol Nurs* 17(3):22-26, 1991.

Dressing for Success: Promoting Independence Among Cognitively Impaired Elderly. Beck C, et al., *J Psychosoc Nurs Ment Health Serv* 29(7):30-35, 1991.

Decreasing Caregiver Assistance for Older Residents with Dementia. Beck C, et al., in *Key Aspects of Elder Care: Managing Falls, Incontinence, and Cognitive Impairment*. Chapel Hill, NC: University of North Carolina at Chapel Hill (in press).

[135] Upper Body Motion Analysis for Amelioration of Falls in the Elderly

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Sponsor: VA Rehabilitation Research and Development Service (Project #E601-RA)

Purpose—The purpose of this study was to develop a wearable accelerometric instrument which would record movements during everyday activities, identify patterns that accompany loss of balance before a fall actually occurs, warn the individual of pre-fall behavior, and if necessary, signal that a fall has taken place. We anticipate clinical use of accelerometric instrumentation to occur in three stages: 1) as a diagnostic tool to quantify hitherto qualitative measures of balance; 2) as a biofeedback device during therapy; and, 3) as a fall-prevention aid (which might be called a "balance orthosis") for continuous use by institutionalized and community-living fall-prone elderly.

Methodology—Subjects wear 3-axis accelerometers attached to the corners of their eyeglass frames to measure head motion, and also attached to a belt at the waist. A self-contained data-acquisition package on a second belt is worn where most comfortable for the user. Sensor outputs are digitally recorded, then analyzed by deriving the antero-posterior (pitch) and lateral (sway) angles of the trunk and head; the time average indicates orientation relative to the vertical, and high standard deviation (SD) indicates unsteadiness. The vector magnitude at each sensor varies from the 1G acceleration of gravity at the start and end of volitional motion, during tremor and uncontrolled oscillation, upon impact such as heelstrike while walking, and during falls.

Progress—During the pilot phase, elderly subjects were found to differ from young subjects by: 1) higher trunk accelerations standing with eyes closed; 2) transmission of more foot impact to the head

while going down stairs; 3) more consistently positive or negative (tilting forward or backward) means and higher SDs of trunk angles during sitting down; and, 4) bimodal sway SDs during rising from a chair.

Current activities include testing of well-defined motion sequences simulating activities of daily living (ADL), expansion of the subject population to include postsurgical patients whose progress is more rapid than other fall-prone elderly, and integration with other balance diagnosis techniques (one such, the "Equitest," will permit controlled induction of falls). A major new activity has been to create a self-administered questionnaire and a physical examination protocol to obtain a thorough medical history for each subject. These and the qualitative assessment protocol for comparison with the accelerometric score include all nonduplicated items from the four most widely used published balance and ADL assessment methods.

Preliminary Results—The wearable data acquisition system has reached the point where it is a reliable and easy-to-use tool. An infrared remote control is used to command the wearable unit so that the wearer is unencumbered by cables. Data rates have been increased from less than 20/sec in the pilot study to 50/sec. Data are transferred for analysis to a fixed computer, which now has software for calibration and calculation of magnitudes and angles in polar coordinates in a single step. This enhanced system has been tested only with young subjects; elderly subjects are being enrolled, with priority given to participants in the pilot study.

[136] Assessment of Age-Related Changes in Visual Spatial Organization

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Purpose—As people age, physical changes occur to their eyes and to the part of the brain that processes vision. Some of these changes seem to relate to the way they see objects in the environment (e.g., difficulty in identifying certain colors, in the recognition of faces, and in the appreciation of depth relationships between objects). Unfortunately, many of the studies reporting these age-related changes in vision have failed to provide a complete vision examination performed on the participants. This study was designed to establish some baseline measures of vision in older people who had no clinical pathology. Using the results of this study, a comparison can be made between the visual performance of older people having no clinical problems and that of individuals having specific visual loss.

Methodology—The 3-year study required the testing of 128 normally sighted people from two age groups: 20–35 and 55–70 years of age. The performance of the participants on a set of clinical and experimental tests of vision was compared with their judgments of distance, depth, and size, in both laboratory and natural environments.

The participants were carefully screened for a large number of age-related visual problems including glaucoma and cataracts. All participants were required to have at least 20/30 corrected visual acuity in each eye. They were also required to be corrected for astigmatism and any muscular problems presenting double vision or a dependency with one eye.

Several laboratory vision tests were administered. Among these tests were examinations of visual acuity, visual field extent, macular stereopsis, contrast sensitivity, and eye alignment in total darkness (tonic vergence). Other experimental tests conducted in darkness required the observers to

make size and distance judgments to familiar and unfamiliar objects presented at a distance of 8.5 m. These judgments were made with the subject standing still and after walking 3.7 m toward the objects. In a natural daylight setting outside of the laboratory building, size and distance judgments were made to rectangles placed at 20.4 and 56.4 m. In another experimental test, the observers viewed an artificial stairway in which the step height varied from 10 to 30 cm. The observers responded by separating their feet to approximate the apparent depth of the steps. Some judgments were made with full vision; others, with a visual loss simulating "tunnel vision" (approximately 14 degrees).

Results—In viewing objects in the darkened laboratory, both groups of participants made large errors of underestimation; however, the younger people made significantly more accurate judgments than the older people. Large underestimations of distance and depth also occurred in the natural settings, but the age effect was reduced. Under darkened viewing conditions, younger people may be better able to utilize certain visual distance cues than are older people. Under daylight, the natural conditions provide many more cues to both the younger and older viewers, and the age differences seem to be greatly reduced. In the stair-step task, both age groups performed well in judging the visual step height. With the tunnel vision presentation, however, the older observers made greater underestimations of the large step heights. Such visual loss is more common to the older person, and this finding may be important in helping to reduce the number of accidental falls by improving architectural features of stairs and by emphasizing aspects of visual training with the older person.

[137] Systematic Observation of Wandering Behaviors in Older People and Contributing Factors

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Sponsor: VA Rehabilitation Research and Development Service (Project #E402-RS)

Purpose—The purpose of this study was to capture and describe the unique patterns of travel of nursing home residents labeled “wanderers,” and to explore the relationships between the expression of these travel patterns and a variety of psychological and nonpsychological factors. The following research questions were addressed: 1) What kinds of travel behaviors constitute wandering activity? 2) How do psychological factors such as dementia and depression affect wandering? 3) Do nonpsychological factors like demography, previous occupational demands, or physical impairments play a role in wandering? and, 4) Is medication an important contributing factor to wandering?

Progress—A total of 40 subjects completed the study protocol at one site. Replication of the results is underway at another site.

Methodology—This study used an automated observational methodology based on video monitoring to capture the travel behaviors of nursing home residents. A portion of these residents had been identified by nursing staff as wanderers. Travel behaviors were evaluated by two independent raters using a reliable coding scheme developed for this study. All participants were evaluated with respect to cognitive and emotional status, demography, and medication regimens. Participants were classified as efficient or inefficient travelers based on travel behavior and were compared with respect to a variety of factors.

Results—Travel was monitored 24 hours a day for 30 days, resulting in the recording of over 5,000 unassisted travel events. Four basic travel patterns were observed: direct travel (86.8%), lapping (11.6%), random travel (0.9%), and pacing (0.7%). Exhibition of these travel patterns was clearly related to cognitive status ($r=0.56$). It was not

affected greatly by subject characteristics or physical demands of previous occupations. Neither was it affected greatly by the presence of clinical levels of depression, nor prescription of psychotropic medication, laxatives, or diuretics. Percentage of inefficient travel was generally low (7–8%) during the day for participants no more than moderately demented, except in the early evening when the rate doubled (“sundowning”). However, for the severely demented, inefficiency of travel was consistently high (30%) regardless of the time of day. Lapping was the most common inefficient travel pattern engaged in by participants exhibiting low travel efficiency (>90%). In fact, for those individuals who exhibited any pacing or random travel, lapping predominated. Therefore, it stands to reason that structured walking programs and/or redesign of environments to safely accommodate independent walking may offer less restrictive and healthier solutions than restraint. The emergence of inefficient travel was interpreted to be symptomatic of later stages of Alzheimer’s disease.

Implications—This study has demonstrated that the travel of wanderers and nonwanderers can be objectively studied. This can be accomplished either by using an automated video-based observational method (as in this study), or in the future by developing the technology to electronically map travel patterns. The hope is that these results will stimulate further research on wandering, particularly with regard to the evaluation of interventions that maximize the travel independence of cognitively impaired older adults without compromising their safety.

Recent Publications Resulting from This Research

Travel Behavior of Nursing Home Residents Perceived as Wanderers and Nonwanderers. Martino-Saltzman D, et al., Gerontologist (in press).

[138] Pilot Study of Balance Training in Elderly Fallers and Nonfallers

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Sponsor: VA Rehabilitation Research and Development Service (Project #E542-RS)

Purpose—The purpose of this pilot study was to determine: 1) the reliability of the EquiTest results among elderly fallers; 2) the validity of the EquiTest to discriminate elderly fallers from nonfallers; and, 3) the effectiveness of visual feedback training using a forceplate to improve postural stability as measured by the EquiTest. Our intent is to gather preliminary data that addresses these objectives so that our longer study can proceed.

Progress—The EquiTest was upgraded for this project with Version 4 of the software and with a new printer. Version 4 software incorporates norms and latencies from an older population, thereby providing a realistic database against which to assess performance in our pilot subjects. The EquiTest, available through the Atlanta VA Rehabilitation Research and Development Unit, was moved to the Center for Rehabilitation Medicine at Emory University School of Medicine. The Balance Master, a device offering visual feedback of force displacements during postural sway was purchased and calibrated.

A technician was trained in both EquiTest and Balance Master operation. Her job responsibilities have been to: assist in obtaining subjects; schedule subjects; assist in assessment of subjects; and, train all subjects in balance control or improvement.

Methodology—Twenty-seven subjects have been pretested and assigned to the following categories:

nonfallers with treatment—12; fallers with treatment—8; and, fallers without treatment—7. Eighteen of 27 subjects (67%) have completed pretesting (6 weeks of treatment or no treatment) and posttesting. The treatment consists of balance training for 1 hour per week. Balance training is performed using the NeuroCom Balance Master, a programmable force platform housing four strain gauges. Recruitment of subjects continues, as 12 subjects is the target number for each category. There is a 4-month interval between the posttest and the follow-up test.

Results—Mortality rate is minimal since only one subject has dropped out. An additional group of five elderly fallers, who are potential candidates for the faller nontreatment group, have been identified. Three potential fallers eligible for training have also been identified.

Future Plans—Our intent is to address the objectives noted above so that minimal “downtime” will exist between this project and activation of our longer study. Shortly, we will begin comparing data of the EquiTest to determine the ability of the EquiTest to reliably detect fallers (Objective 1); to see if a change in measured force value truly discriminates fallers from nonfallers (Objective 2); and, any change in EquiTest force values as a function of balance training (Objective 3).

[139] Knowledge-Based System for Selecting Elopement Control Devices

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Sponsor: VA Rehabilitation Research and Development Service (Project #E596-2RA)

Purpose—In order to provide safer environments for dementia patients who wander, this study will develop a knowledge-based system to aid in selecting

devices to control elopement in nursing homes. The study will produce a computerized database that uses data from field studies and expert judgments. It

will serve as a basis for matching the most effective types of interventions when given a building design, staffing patterns, policy, and patient profiles. The knowledge base is intended for use by administrators and health facilities designers in selecting appropriate interventions for a specific facility.

Progress—Site visits have been completed at 14 skilled nursing facilities/special care units. The large majority of the site visits have been conducted at VA facilities. Additional site visits are being completed at private skilled nursing facilities in the Atlanta area. Data on the technical specifications of commercially available electronic alarm systems have been obtained and compiled. The initial iteration of the expert system has been completed.

Methodology—This study entails a five step process to: 1) identify prototypical facility descriptions (including typical building layouts, staffing patterns, institutional policies on wandering, and patient profiles); 2) obtain recommendations from health care and facilities experts on the requirements for elopement control devices; 3) identify products that meet the stated requirements; 4) evaluate the responsiveness of the commercially available devices in meeting the stated requirements; and, 5) create the knowledge-based system.

Site visits will be conducted at 15-24 skilled nursing facilities as a basis for developing the prototypical descriptions. The skilled nursing facil-

ities will be selected on the basis of the overall building plan and configuration of patient care units. Data obtained through the site visits will provide the basis for the preliminary knowledge system. A meeting of health care and facilities experts will be convened to review and revise the knowledge system in terms of its ability to address realistic problems with elopement that confront nursing home administrators. Manufacturers of commercially available electronic alarm systems will be contacted to obtain descriptions of existing systems. This information will be integrated into the knowledge system.

Results—Seven building design factors have been identified that affect opportunities for elopement. These are: location of entry/lobby area; sight lines of egress routes from spaces frequently used by staff; number and location of exits; location of frequently used spaces (e.g., dining room); length of corridors; interior circulation system; and provision of outdoor spaces. Admission and transfer policies were found to have important consequences for the magnitude of the elopement problem at any given facility. Staff at facilities that do not have alarm systems frequently reported a desire for such systems. Staff at facilities with alarm systems reported that these systems often have unexpected negative consequences for staff and patients. These consequences include false alarms and the noise annoys patients and staff.

[140] Physiological and Functional Benefits of Two Exercise Programs for Older Adults

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Sponsor: VA Rehabilitation Research and Development Service (Project #E628-RA)

Purpose—Involving older adults in regular activity and exercise has become a highly promoted goal in gerontology. However, many exercise regimens have not been adequately evaluated. The purpose of the study is to scientifically examine differences in the acceptability, appropriateness, and effectiveness of: 1) Tai Chi, a widely practiced exercise activity program for all age groups in Far Eastern cultures; and, 2) a structured walking program, the most

commonly recommended activity for older adults in our society. This study will empirically evaluate and compare the functional, physical, and psychosocial benefits of these two exercise programs for older adults, as well as the acceptability of Tai Chi as an exercise option for American-born older adults.

Progress—A group of 37 subjects have completed the study protocol (exercise reversal and testing).

Recruitment and pre-testing for the second group of subjects (N=36) is completed and the second exercise protocol has begun. The data from the first group of subjects have been compiled and analysis of the first group has been done. Production of the instructional videotape for Tai Chi is in progress.

Methodology—The research plan is to compare the benefits of walking and Tai Chi for older adults by conducting these interventions at two community sites. A variety of psychological, exercise physiology, and attitudinal measurements will be collected prospectively. In addition to between-group comparisons, reversal of the interventions will allow within-group comparisons and an objective evaluation of perceived benefit. To complete this research, small groups of community dwelling adults at two sites have been randomly assigned to one of two traditional exercise programs three times a week for 12 weeks (total N=60). The subjects are recruited from open-enrollment community-sponsored programs. One half of the participants will be enrolled in a guided walking program. The other half of the participants will be enrolled in a Tai Chi exercise program. After the initial 12 weeks, the exercise intervention will be reversed. Comparisons of the physiological, psychological, and functional benefits

of each exercise program will be made after the first 12 weeks using a two-group repeated measures design. Attitudes about each exercise will be assessed after reversal (24 weeks) and 6-months post-intervention. Continuance will only be evaluated at the follow-up assessment. The entire protocol is being replicated to attain the proposed number of participants.

Results—Data for the first phase of the study have been entered for statistical analysis. Results are not available at the present time.

Future Plans/Implications—Based on the findings of this study, the investigators will develop a curriculum and video materials for an innovative exercise program for older adults that promotes continuance in beneficial exercise programs. Results of this study would be of value to health care practitioners and exercise/behavioral scientists to prescribe exercise options for older adults.

Recent Publications Resulting from This Research

Physiological and Functional Benefit of Two Exercise Programs for Older Adults. McNeely E, Sharon B, in Proceedings of the 38th Meeting of the American Society on Aging, San Diego (in press).

[141] Applicability of Accessibility Codes to Meet the Needs of Elderly People

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Sponsor: VA Rehabilitation Research and Development Service (Project #E629-RA)

Purpose—This project is the first in a series that is concerned with the applicability of accessibility codes to meet the needs of elderly people. Specifically, this study will examine several components of environment design that have implications for the safety and independence of elderly people in toileting. Difficulty in toileting independently is common among both ambulatory elderly people who have difficulty raising and lowering themselves on and off the toilet, and nonambulatory elderly people who have difficulty transferring between the toilet and wheelchair. In response to these problems, this study will use a task performance and analysis

to evaluate the impact of bathroom design on toileting activities.

Progress—A full-scale mock-up of a toilet room has been designed and preparations have begun for its construction. The mock-up will have interchangeable grab bars, an adjustable height toilet, and will be easily broken down for transporting to field test sites.

Methodology—Differences in the safety and independence afforded by different grab bar/toilet height configurations will be addressed by a re-

peated measures design. Eight toilet room designs (four grab bar configurations, paired with two variations in toilet seat height) will be evaluated. A stratified random sample of 34 ambulatory and 34 nonambulatory elderly participants who toilet independently will simulate toileting activities in each of the eight designs. The sample will be drawn from residents of independent living, assisted living, and nursing home settings in the Atlanta area. Persons who require assistance in toileting will be excluded from the sampling pool.

Subjects will be instructed to enter the toilet room mock-up, approach the toilet, sit down/transfer to toilet, rise/transfer to wheelchair, and exit the toilet area. The order in which the toilet rooms are evaluated will be randomized across subjects. Participants will be told to proceed at their own pace and permitted to rest between each trial. Participants will be interviewed regarding the perceived safety and independence of the design configurations

(e.g., How safe did you feel while getting on and off the toilet?). The self-report data will be obtained in a brief interview that will be repeated after each trial.

Two video cameras will be used to record participants simulating use of each toilet room mock-up. The video-based data will be coded using scalar rating categories of safety and independence to be developed by an Occupational Therapist. The coding system includes issues such as location of body when undertaking a task (as measured by the wall grid system), ratings of upper body range of motion required to use a given grab bar, location of hand on grab bar, and location of body in relation to the toilet. Video tapes will be scored by two independent coders. Inter-rater reliability will be statistically determined using Cohen's Kappa. A minimum Kappa of 0.6 will be required before retraining.

[142] Environmental and Behavioral Factors in Falls Among the Elderly

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Sponsor: VA Rehabilitation Research and Development Service (Project #E539-RA)

Purpose—The specific aims of this study are to: 1) identify and describe the role of salient environmental and behavioral factors in fall and near-fall events among institutionalized elderly persons; 2) compare the relative accuracy of primary data on fall events (e.g., video records) with post-incident self-report data (e.g., verbal reconstructions by the fallers) and secondary data (e.g., falls-incident reports); and, 3) assess the acceptability of the data collection methodology from the perspective of the participants. The long-term objective of this study is to use research to design and evaluate interventions which help to reduce the occurrence of falls among the elderly.

Progress—Five data collection cycles of four subjects each have been completed. Four more data collection cycles are planned.

Methodology—The study is being conducted at the Atlanta Department of Veterans Affairs Medical

Center Nursing Home. Current residents with a history of falling have been invited to participate. This pool of potential participants will be supplemented, over the course of the study, with new residents who have a history of falling, and current residents who develop a problem with falling. Motion-activated video technology will be used to record naturally-occurring fall and near-fall events. No falls will be induced. Participants' nonfall incidents, matched on intended activity and time of day, will serve as control data. Background information will be obtained on the visual, sensory, neurological, and cardiovascular functioning of the participants using accepted clinical procedures. In addition, the overall health status and current medications of the participants will be documented.

Video technology will be used to record all activities in participants' rooms, including fall, near-fall and nonfall events, for a period of approximately 2 months. Following a fall or near-fall, participants will be interviewed to reconstruct the

event from their perspective. Falls-incident reports (completed by nursing home staff) also will be obtained. An exit interview with each participant will determine attitudes of the participants toward the video methodology. Environmental and behavioral factors involved in fall and near-fall events will be coded and statistically analyzed. The role of architectural characteristics will be further examined using floor plan analysis techniques.

Results—To date, a total of 66 fall and near-fall incidents have been observed. Slightly more than 20% of the incidents are falls, and slightly less than 80% are near-falls. One fall has resulted in a serious injury (fractured femur).

[143] Why Don't All Impaired Elderly Fall?

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Sponsor: VA Rehabilitation Research and Development Service (Project #E538-RA)

Purpose—The purpose of this study is to test the hypothesis that impaired mobility is a necessary but not sufficient risk factor for recurrent falls. Falls risk is proposed to be modified in impaired persons by nonphysical behavioral, social, and environmental risk factors.

Methodology—Male veterans aged 70 or older received baseline assessments of mobility, behavioral, social, and environmental factors and were followed for 6 months for falls.

Results—Results are of follow-up of 251 subjects recruited through the end of 1990. Based on

mobility status at baseline, 136 were deemed high-risk and 115 deemed at low-risk. One or more falls occurred in 52 (38.2%) of high-risk and 14 (12.2%) of low-risk subjects ($p < 0.0001$). Recurrent (two or more) falls occurred in 27 (19.8%) of high-risk and 3 (2.6%) of low-risk subjects ($p < 0.0001$). Within the high-risk group, risk for both one or more or recurrent falls was significantly modified by behavioral and environmental, but not social, factors by initial logistic regression analyses that also controlled for mobility, age, and cognition.

[144] Integrated Assessment of Factors Affecting Functional Status and Fatigue

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Sponsor: VA Rehabilitation Research and Development Service (Project #B614-RA)

Purpose—As disabled patients age and experience concurrent age-related reduction in physiological functions, fatigue and energy conservation become primary concerns in optimizing function. We need to know both absolute and relative VO_2 in order to understand activity limitations and to make assessments of devices and treatment programs. The well-established linear relation between energy consumption and heart rate can aid us in this task.

Individuals differ in the slope and intercept of the heart rate- VO_2 relationship. Therefore, our task becomes one of establishing slope and intercept as simply as possible.

Energy expenditure during walking can be determined for normal persons using equations developed by exercise physiologists over the past 40 years so that specific measures of energy expenditures at submaximal activities are no longer neces-

sary. Such equations are also used for rehabilitation after heart attack in persons without other physical disabilities. However, no similar model exists for persons with traumatic injuries. While the linear relation between oxygen consumption and heart rate is maintained, the differences in physical abilities have not allowed the data from disparate individuals to be combined until recent work with spina bifida. There, the same general equations were found to apply regardless of the presence of partial or complete paralysis of the legs, and the same equations applied to walking and to wheelchair locomotion. Recent work by this team indicates that these same equations hold for normal adults, adults with multiple sclerosis, and above-knee and below-knee amputees. However, the variables that influence this important heart rate-VO₂ relationship have not been well-studied in disabled persons.

This key relation of the project—the way heart rate changes in proportion to physical work—is clearly mediated via the autonomic nerves. Abnormalities of these nerves, as occur in diabetes, are associated with higher mortality rates. This study will use recent, noninvasive measures of autonomic activity to examine the effects of altered autonomic function on the capacity for work. Another limiting influence on treadmill walking and running in normal persons is the ability to use the larger leg muscles associated with this activity. Most of the total oxygen consumption of the body during walking or running is attributable to these muscles. In disabled patients, however, fatigue of already

weak muscles may occur with compensatory changes in oxygen consumption because of reduced muscle mass. Therefore, measures of muscle strength and fatigue will be included in the assessment of functional limitation. Finally, it is important to obtain a picture of the activity level that patients achieve in their normal activities. Therefore, outpatient activity monitors will be used to extend our assessments beyond the clinic and laboratory.

Methodology—One hundred and twenty subjects (90 with lower limb amputation and 30 nondisabled adults) will be tested on a treadmill to determine their functional capability and the metabolic, autonomic, and muscular contributions to it. Half of the subjects in each group will be given a 4-month exercise program, and all subjects will be retested at the end of 4 months. During testing and the inter-test interval, subjects will wear a small self-contained activity monitor which will provide information on their pattern and level of activity. The information will be synthesized into practical models that can be used to: 1) profile contributions to the fatigue and functional limitations of a patient; 2) predict the levels of energy expenditure that the patient can expect to attain; and, 3) provide some information about the daily pattern and intensity of activity of the patient. These models will be used to examine the effects of the exercise program. Further, they should ultimately provide a means of testing and tailoring a variety of prescriptions for assistive devices and other treatments.

[145] Age-Related Changes in Sensory-Motor Performance

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Purpose—The goal of this research is to achieve an integrated understanding of the changes which occur in sensorimotor performance as healthy people grow older. These data are being used to identify functional differences in elderly individuals who are "at risk for falls," or who have a history of unsteadiness or falling.

Methodology—A database of performance measures of healthy aging subjects, ages 45-84 years has been

developed. We are objectively evaluating the neuromuscular system (myotatic reflexes, joint compliance, muscle strength, simple ankle joint voluntary movements, somatosensory evoked potentials), and systemic functional integrity (standing balance and gait). The same measures are being performed on elderly community dwellers and residents of the Geriatric Nursing Unit who are unsteady and have a history of falling.

Progress—We are evaluating sensory and motor changes in patients at risk for falls, and comparing these data against our healthy aging subjects; most of the healthy elderly subjects are physically active, but have deficits in at least one of the test measures. Sensory and motor changes are also being correlated in healthy aging subjects with deficits in standing balance and gait. Some of our individual test measurements, as well as correlation studies of sensory and motor deficits with balance and gait measures, will be useful mechanisms to discriminate “healthy” aging from individuals who are unsteady or at risk for falls.

Results—In healthy aging subjects, nine types of deficits in biomechanical, electrophysiologic, neurologic, and functional parameters have been identified: 1) absent or delayed reflexes; 2) impaired tandem walking; 3) reduced velocity of gait; 4) altered joint interactions in gait; 5) reduced reaction times; 6) altered joint compliance; 7) muscle weakness; 8) impaired sensation; and, 9) frontal release signs. We consider these deficits as risk factors for falling and unsteadiness. The types, prevalence, incidence, and magnitude of risk factors in older subjects who do not feel unsteady will be compared with those who feel unsteady or have a history of falls.

The gait of 12 unsteady “frail” elderly nursing home residents has been evaluated. These patients, ages 62-100 years, are generally deconditioned and do not have neurological or orthopedic diseases. For this population, all kinematic measures of gait (gait cycle duration, percent stance, stride length, velocity, and equivalent cadence) are significantly different from measures for healthy elderly subjects. In

those patients who demonstrated increases in muscle strength following exercise, commensurate improvements in gait kinematic measurements were measured.

Future Plans/Implications—Our research demonstrates that a diversity of changes may occur in active, aging persons who do not have neurological or orthopedic diseases. Older persons who feel unsteady may have a number of sensory, motor, or neurological deficits which put them at risk for falling. We suggest that the aging process and risk factors for unsteadiness are multi-faceted problems. A goal of our comprehensive, multi-dimensional studies is to identify routine tests which clinicians can use to identify and treat patients at risk for falling, and that therapeutic regimes can be developed to prevent, treat, or compensate for deficits which place elderly people at risk for falls.

Recent Publications Resulting from This Research

- Determining the Frequency Content of Gait Kinematic Measurements: Implications for Data Acquisition and Analysis. Myklebust B, Myklebust J, Prieto T, Sixth East Coast Clinical Gait Conference, East Lansing, MI, 1990.
- Changes in Motor Function in the Elderly: Gait, Balance and Joint Compliance. Myklebust JB, et al., 13th Annual Conference of the IEEE Engineering in Medicine and Biology Society, Orlando, FL, 1991.
- Intra-Subject Reliability Measures of Postural Steadiness. Prieto TE, et al., Seventh Annual East Coast Clinical Gait Conference, Richmond, VA, 1991.
- Sensory-Motor Performance Changes in Healthy Aging Subjects. Myklebust B, et al., Soc Neuroscience Abstr 17:1032, #410.8, 1991.
- Spectral Analysis of Involuntary Muscle Spasms in Spinal Cord Trauma Patients. Burger M, et al., 13th Annual Conference of the IEEE Engineering in Medicine and Biology Society, Orlando, FL, 1991.

[146] Physical Exercise Profile (PEP)

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Sponsor: VA Rehabilitation Research and Development Unit (Core Funds)

Purpose—The assessment of physical activity has become a major challenge of health-focused research because of its association with physiological, personal, and social improvement. The Physical Exercise Profile (PEP), a 41-item self-report instru-

ment, was developed to specifically address these concerns in assessing older adults. The PEP provides individual descriptive profiles consisting of seven subscale scores, a Total PEP score, and an individualized prescription (PEP-Plan). From a

practical perspective, the PEP is easy to administer, requires only 20–25 minutes, and can be used in a wide variety of settings. Further, it successfully differentiates between subjects with high and low physical fitness levels on most scales with minimal risk and at a lower cost.

Progress—The PEP has been administered to 53 females (age 27–81, mean: 60.8 years), and 38 males (age 22–84, mean: 58.5 years), recruited from a large Southeastern metropolitan area. Fitness data also were obtained via body composition assessment and submaximal treadmill or bicycle ergometer testing.

Methodology—Subjects were ranked from high to low according to their fitness level, defined as estimated maximal oxygen capacity adjusted for age and sex. Using this ranking, two groups of subjects were identified. The high fitness group was comprised of the 30 subjects who had the highest fitness levels, whereas the low fitness group was comprised of the 30 subjects who had the lowest fitness levels. The PEP yields a Total PEP score and seven scale scores: Current Exercise Level (less than 1 month), Past Exercise Level (1 month to 1 year), Exercise Predictor, Health Status, Physical Fitness Knowledge, Accuracy of Body Image Perception, and Socioeconomic Status. In addition to the total and subscale scores, the PEP-Plan is provided, enabling the design of individualized exercise programs. This information is derived from subjects' responses to some of the 35 items on the subscales and an additional six items which do not contribute to the scale and total scores. In sum, the PEP provides individual descriptive profiles consisting of the seven subscale scores, the Total PEP score, and PEP-Plan.

Results—Internal reliability for the PEP Total score was adequate (Cronbach's $\alpha = 0.90$). The internal reliability coefficients for five of the seven subscales were also considered acceptable. The test-retest correlations for the subscales ranged from 0.81 to 1.0. Two groups of subjects were identified to evaluate the validity of the PEP ("high fitness" group, $n = 30$; "low fitness" group, $n = 30$). MANOVA tests revealed that many of the scales were valid predictors of fitness. Research continues to improve the validity and reliability of the PEP.

Future Plans/Implications—As one of few comprehensive exercise assessment tools available today, the PEP will: 1) evaluate the person's total exercise profile; 2) be standardized for ages 20–100; and, 3) help determine an appropriate exercise regime for the individual. This initial investigation supports the reliability and criterion-related validity of the PEP. The exercise testing used in this study to determine the level of physical fitness was expensive and physically demanding. In contrast, the PEP successfully differentiates between subjects with high and low physical fitness levels with minimal risk and a much lower cost. This tool is easy to administer, requiring only 20–25 minutes, and can be used in a wide variety of settings. Consequently, the PEP has the potential to be a highly practical, reliable, and valid instrument for measuring physical exercise habits.

Recent Publications Resulting from This Research

Development of an Exercise Evaluation Tool for Use with Young to Older Adults: Physical Exercise Profile. Cannella K, et al., The Gerontological Society of America (GSA), 1991.

Physical Exercise Profile (PEP): A Reliability and Validity Study. Boyette L, et al., The Southern Council on Collegiate Education for Nursing (SCEEN), 1991.

[147] Balance and Posturography Testing

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Sponsor: VA Rehabilitation Research and Development Unit (Core Funds)

Purpose—We are concerned with developing and enhancing a technique for measuring balance abnormalities in patients. The laboratory evaluation of

disequilibrium has primarily depended on assessment of vestibulo-ocular reflexes and on stimuli that affect the horizontal semicircular canals. The recent

development of posturography provides another diagnostic tool, and extends the laboratory assessment to vestibulo-spinal reflexes that play a central role in posture and balance.

Progress—A commercial dynamic posturography system, EquiTest (NeuroCom International, Inc., Portland, OR) has been evaluated in large numbers of patients complaining of dizziness, vertigo, or disequilibrium. Some of these studies suggest that the standard EquiTest protocols have only a moderate sensitivity and specificity for disorders of balance, including diseases of the vestibular system. Our experience with more than 250 patients and 150 volunteers has been similar; thus, we have pursued modifications that might enhance the diagnostic capabilities of dynamic posturography.

Methodology—We first used the EquiTest dynamic posturography system to test the effect of 55-degree head extension on postural sway in 20 normal subjects. There was a highly significant increase in sway with head extension under two conditions. In both conditions, the support surface moves proportionally to body-sway angle (sway-referenced feedback). The largest increase in sway occurred when the eyes were closed and the support surface was sway-referenced. This latter condition removes vision, reduces the effectiveness of ankle proprioception, and forces the subject to depend mostly on vestibular information for equilibrium. We suggested that head extension increases sway because the utricular otoliths are put into a disadvantageous position. (This work has been published.) Since this early study, we have tested an additional 60 normal volunteers with head extension. The results obtained with the first group of 20

has held firm for the second group of 60.

We selected volunteers in various age decades to determine if the head extension is age-related. In our second publication, we showed that if the testing is done with head erect, subjects below 60 years do not lose their balance during testing. However, if the head is extended during testing, subjects in their late 40s lose their balance. The main purpose of the second publication was to demonstrate that we can increase the sensitivity of dynamic posturography by adding head extension and sway energy measurement to the standard EquiTest protocol. Both procedures were applied to 121 patients and to 89 normal subjects. Using the formula, $\text{Energy} = \text{Force} \times \text{Distance}$, and appropriate corrections for platform tilt and body weight, any previously recorded test can be analyzed with computer programming to give energy values in joules/kg. Adding the two criteria is useful in separating symptomatic from asymptomatic subjects and patients.

Results—We are investigating the physiological implications of chaos theory to the problems of natural and induced falls by normal subjects and patients with disequilibrium. We are applying our enhancement techniques (head extension and sway energy measurement) to groups of patients with the same diagnosis (e.g., Ménière's disease) to determine if we can aid in their differential diagnosis.

Recent Publications Resulting from This Research

Effect of Head Extension on Equilibrium in Normal Subjects. Jackson RT, Epstein CM, *Ann Otol Rhinol Laryngol* 100:63-67, 1991.

Enhancement of Posturography Testing with Head Tilt and Energy Measurements. Jackson RT, Epstein CM, *Am J Otol* (in press).

[148] Analysis of Spinal Pain in the Elderly: Incidence of Herniated Lumbar Disc

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Sponsor: AARP Andrus Foundation

Purpose—A retrospective analysis of 661 patients in the age range 54 years and over was carried out to

characterize the problem of spinal pain in the elderly.

Progress/Methodology—A subgroup of 128 patients (19.4% of 661) was identified as having lumbar disc herniation. Ten (7.8%) of the patients with lumbar disc were in the 54-64 years of age group, 79 (61.7%) were 65-74 years of age, and 7 (5.5%) were 75+ years of age. Gender breakdown was as follows: 62 males (48.4%), 65 females (50.9%). Association of herniated lumbar disc with central canal and/or severe foraminal stenosis occurred in 58 (45.3%) cases. In addition, 53 (41.4%) of the patients with lumbar disc herniation also showed radiographic evidence of osteoarthritic degenerative changes (but without stenosis). Trauma was the inciting event associated with the onset of pain in 62 cases (48.4%).

Results/Implications—Radiological confirmation of disc herniation was as follows: 100 cases (78.1%) were confirmed by CT, and 54 (45.3%) were confirmed by MRI. Multiple disc herniations in the lumbar (or other areas of the spine) occurred in 32 (25%). Six of the patients (4.7%) had recurrent disc herniations at the time of their initial presentation. EMG/nerve conduction identified a radiculopathy in 23 cases (18%). The incidence of herniated disc in the elderly appears greater than generally appreciated and is associated with stenosis in nearly half (45%) of the cases.

[149] Do Changes in Strength Improve Balance and Function in Elderly Men?

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Sponsor: VA Rehabilitation Research and Development Service (Project #E661-RA)

Purpose—The purpose of this study is to determine if improving lower extremity strength in impaired older veterans reverses functional deficits.

Methodology—One hundred male veterans aged 70 or older who met criteria for mobility impairment and lower extremity weakness were randomized to treatment or control arms. The treatment is an 8 week in-home supervised exercise program of pro-

gressive resistance exercise using body weight and Theraband, incorporating concentric and eccentric contractions at functional velocities. Baseline and outcome measures were designed to assess change in strength, balance, physical performance, and function using state-of-the-art laboratory instrumentation, standard report instruments, and a newly designed measure of personal functional goals.

[150] Home Safety for Urban Frail Elderly: A Pilot Study

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Sponsor: Metro Health Foundation

Purpose—Our pilot project was designed to identify and remove safety hazards in the homes of a small group of elderly residents at high risk for falls and burns, and to gather data about the extent to which this service prevented accidents and reduced health-care costs. Residential injuries (falls, burns, poisoning, suffocation, etc., occurring in the home and the

immediate surroundings) are a major public health problem in the USA. Residential injuries are most common to the very young and the very old. Injuries rank sixth as a cause of death among people 65 to 74 years of age, and seventh among those 75 or over. An estimated 18 percent of seniors 75 years of age or over suffer injuries in the home each year.

A promising method for preventing residential injuries to the elderly may be the "home safety audit" or "environmental hazard inspection program." However, empirical studies of the outcomes and cost-effectiveness of home safety audit programs are not yet reported in the literature.

Progress/Methodology—During the course of the study, we received 159 referrals from community agencies. All persons referred were age 60 or older and living in a potentially hazardous home environment. Most had health problems that increased the risk of accidents and injuries (e.g., arthritis, cataracts, hypertension). Median annual income of the seniors referred was about \$7,000.

Each person referred was oriented to the program by letter and/or telephone call. The first 40 seniors who expressed interest in participating were visited in their homes by an interviewer. Informed consent and baseline data about health, independence, and living situation were obtained. After the interview was completed, the senior was randomly assigned to either a control or service group. Persons in the service group were visited by an occupational therapist and a carpenter, who evaluated their homes room by room for potential safety

problems. Findings were explained to residents, supplies and equipment were purchased, and repairs were made to the extent possible within time and budget constraints.

The project team spent six to twelve hours in each of the 18 homes assigned to the service group. Most of the homes were old and in serious disrepair. The modifications made most frequently included installing smoke alarms, grab bars and banisters, improving lighting, and repairing or removing floor coverings.

Preliminary Results/Future Plans—Follow-up interviews were completed six months after each senior entered the study. Preliminary findings are that persons in the service group improved (but not to the level of statistical significance) in ability to manage everyday activities independently and in attitudes toward their housing situations. No differences were found in the number of serious injuries reported by seniors in the two groups.

Larger scale research is planned to investigate the incidence of minor accidents in the home and their relationship to loss of independence among the elderly.

[151] Reducing Frailty in Elders: Two Exercise Interventions

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Sponsor: National Institute on Aging, National Institutes of Health

Purpose—This study is part of a program of research to evaluate a variety of interventions to reduce falls and frailty in older people. It is using carefully matched samples of elderly subjects to determine the relation of: a) individual, static exercise (balance training) to frailty in an elderly sample; and, b) participation in a dynamic group exercise program (modified after the principles of Tai Chi) to frailty in an elderly sample. Clinical and functional measures are being used to evaluate the relation of the interventions to frailty. The Rehab R&D Center on Aging, Atlanta VA Medical Center, is documenting the physical characteristics of subjects' homes that are thought to be relevant to functional measures of frailty in older people.

The detailed documentation of the home environments of a substantial number of elderly people is intended to serve several purposes. First, little is known about the housing environments of older people, and documentation of the housing of a large number of participants will be informative in its own right. Second, it is anticipated that these data will be useful in interpreting pre/post measures for some subjects. If there are cases in which the expected pre/post reported reduction in difficulty with kitchen tasks is not obtained, physical measures data may help to explain these results.

Methodology—The protocol being used was adopted from one developed by the Center on

Accessible Housing (CAH), North Carolina State University to characterize the home environments of persons of all ages with disabilities. As in the case with the CAH protocol, the physical measures of design features (e.g., height of kitchen cabinets) obtained through the study are conceptually linked to tasks (e.g., getting dishes out for a meal) that are part of a sequence that makes up routine household activities (e.g., meal preparation). Further, many of the tasks related to the design features being measured involve body movements that one can hypothesize will be impacted by the Atlanta exercise interventions—reaching, bending, rotating, dynamic and static balance, stamina, etc. The pre/post intervention interview asks for self-reported ratings of difficulty with household tasks and activities that involve these movements.

In addition to measuring the plan of the house,

measures of elevations also are being obtained for kitchens, bathrooms, and storage areas such as closets. Stairs, where present, are being documented. Interior spaces as well as selected exterior features, such as entries to the dwelling and path to the mailbox, are being photographed. Finally, visiting people's homes for the express purpose of documenting it as a physical object often evokes unsolicited comments about how well it works for them. These comments are often informative in terms of the "fit" between the dwelling unit, and the abilities and lifestyle of its occupants.

Progress/Results—Physical measures and a photographic record have been completed for 58 subjects. Documentation will continue as additional waves of subjects are admitted to the study. Data analysis has not yet commenced.

[152] Attitudes Of and Toward Older Persons with a Disability: Their Measurement and Role in Rehabilitation

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—Psychological and social factors can have an effect on attitudes toward disability, old age and rehabilitation. Patients' self-attitudes may influence their motivation during the rehabilitation program and follow-up; family attitudes may affect the support and assistance given to the patient; and physician attitudes may determine the types and aggressiveness of rehabilitation goals set for patients, including whether rehabilitation is considered to be beneficial or even appropriate. Therefore, this project has three major objectives: 1) development and validation of a new scale to measure attitudes toward disabled older adults; 2) validation and testing of an existing scale that measures the attitudes older adults have toward their disability experience; and, 3) investigation of the impact of family, physician, and patient attitudes on the rehabilitation progress and outcome for disabled geriatric inpatients.

Progress—The major activities of this project have been the development and validation of two attitude scales.

The first scale, Attitudes Toward Older Adults with Disabilities scale is in its final stage. Scale development and wording of items were based on Rosenberg and Hovland's concept of attitudes as a comprehensive variable consisting of three components: belief, affect, and behavioral intent. Previous attitude scales have tended to measure only one or two of these attitudinal elements. This scale has items that cover the topics of social, psychological, functional, and societal attitudes and personal reactions toward the disabled older adult. Reliability, validity, and norm data are being collected on a sample of 300 community residents.

Linkowski's Acceptance of Disability scale measures disabled adults' self-attitudes toward disability and is based on Wright's acceptance of loss theory. This scale was developed for and has been used primarily with the younger disabled population. Since disability concerns and experience of older disabled adults can differ from those of younger ones, it cannot be assumed that this scale automatically addresses self-attitudes relevant to the elderly. Validity and reliability testing of this scale

when used with an older disabled population is in progress.

Future Plans—The fourth and fifth year of the project will utilize the developed and validated scales

mentioned above to investigate the role and influence of attitudes in geriatric rehabilitation. A technical manual on the creation, norms, and validity of the Attitudes Toward Disabled Older Adults scale will be available through this center.

[153] Later-Life Effects of Early-Life Disability: Comparisons with Age-Matched Controls on Indicators of Physical, Psychological and Social Status

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—Although most persons with disabilities can now expect to live to later life, many are experiencing the onset of new health and functional problems. Two of the largest groups suffering from these secondary disabilities are people with post-polio and spinal cord injury (SCI). Post-polio individuals are experiencing primarily fatigue, weakness, pain and loss of strength. The SCI population is encountering multiple medical problems such as osteoporosis, hypertension, renal disease, and cardiovascular and respiratory problems. Despite their potential implications, little systematic research has examined the long-term consequences of these early-life disabilities.

The purpose of this project is to conduct a well-controlled study comparing two groups of early-life disabled individuals (post-polio and SCI) with age-matched non-disabled controls and late-onset disabled persons (such as those with stroke and diabetes).

The objectives of this study are two-fold. The first focuses on a variety of medical, psychological, and social variables in order to: 1) determine if there are differences among the four subject groups; and, 2) evaluate to what extent the changes reported are due primarily to aging, duration and severity of initial disability, or a combination of factors including social support and lifestyle factors (e.g., muscle overuse and substance abuse). Second, aging persons with an early-life onset disability will be studied to: 1) determine if there are gender differences in health and functional changes associated with aging and/or lifestyle; 2) determine the kinds of services

needed in order to continue their independence in the community; and, 3) test a compensation hypothesis as a major factor in late-life sequelae to early-life onset of disability.

Progress—Major activities have focused on subject identification and recruitment, data collection, instrument revision, and creation of a computerized sample accounting and data management system. This system will monitor the status of both individual subjects and subject groups; facilitate age-sex matches across subject groups; and characterize the disability status of polio, SCI and stroke subsamples for comparison with other empirical studies.

Three new data collection procedures also were introduced this year. They include: 1) a social evaluation to assess family solidarity and social support; 2) an activities questionnaire to measure changes over time in general physical functioning, ADL's and recreational activities; and, 3) bone density testing to assess risk of osteoporosis.

With a final goal of 275 subjects, the sample to date equals 190, including 113 post-polio subjects, 25 SCI, and 52 healthy controls. Recruitment for the late-onset disabled group is currently under way.

Future Plans—The fourth year of the project will center on completion of data collection, data processing, preliminary statistical analysis, and dissemination of findings via conference presentations and journal articles.

[154] Policy and Funding Alternatives to Promote Community and Supportive Services for Older Persons with a Disability

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Sponsor: National Institute on Disability and Rehabilitation Research

Purpose—This study was designed to investigate alternative methods of funding programs which will maximize the independence of older disabled persons in their own homes and community settings. The product of the study will be a series of recommendations for implementation or further demonstration and investigation.

The objectives of this study are to: 1) examine current policies and financing mechanisms affecting geriatric rehabilitation of older persons; 2) identify obstacles and barriers that may alter funding for home health and community-based services as well as rehabilitation services to older persons; 3) identify alternatives in financing of geriatric home support and community services; and, 4) recommend alternative methods of financing a variety of these services.

Methodology—The project has utilized extensive literature review, surveys, and legislative analysis in compiling detailed information regarding existing policies and services related to geriatric rehabilitation.

Progress—A comprehensive inventory of existing programs and legislation has been compiled including laws, regulations, statutes, executive decisions, and hearing transcripts regarding policies concerned with rehabilitation services and/or aging services. A

computerized database of relevant current literature has also been established. Surveys of federal legislative staff were completed in 1990 regarding their knowledge and opinions of geriatric rehabilitation. In 1991, a survey of state level governmental agencies and advocacy organizations was completed regarding rehabilitation programs implemented and administered at that level.

Preliminary Results—At present, public policies regarding geriatric rehabilitation exist in two "streams": rehabilitation and aging. The surveys of legislative staff have shown that there is little knowledge regarding the provision of rehabilitative services to older persons, although there is widely held awareness of the need to address the chronic care needs of this population.

Future Plans—The third year of the project was devoted to completing survey work of federal executive branch staff and state rehabilitation program staff regarding geriatric rehabilitation policy and services. In the fourth year, the project will be developing and publicizing alternatives for providing and financing geriatric rehabilitation services. Project staff will also be providing information to federal legislators during the 1991 reauthorizations of the Rehabilitation Act of 1973 and the Older Americans Act.

[155] Use of Technology to Promote Rehabilitation of Older Persons: Reducing Barriers to Independence

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Sponsor: National Institute on Disability and Rehabilitation Research

Purpose—A disability exists when there is an imbalance between what a person with a motor, sensory, or cognitive impairment is able to do, and the demands of the particular task he or she is trying to perform.

One strategy to improve performance and increase the ability of a disabled individual is to use technology to decrease the demands of a task. This can be accomplished either through task redesign or

simplification, or through the use of devices or equipment which enhance the abilities of disabled persons.

Despite recent advances in technology, comparatively little has been done to apply technology to problems of older persons with disabilities. This project addresses safety considerations at home through the application of technology to older persons with limited abilities.

The objectives of this study are to: 1) survey existing products and publish a pamphlet of ideas and products that can be used to improve safety in the home, especially safety relating to falls, burns, and medicine consumption; 2) generate criteria for appropriate features of medicine organizing/dispensing devices for older users; 3) evaluate a range of medical organizing/dispensing devices (from low tech to high tech) against these criteria; and, 4) develop guidelines for consumers and manufacturers detailing those factors of medication organizing/dispensing technologies appropriate for

older persons with ranges of cognitive, sensory, and motor impairments.

Progress—The initial survey of existing technology has been completed and the technologies identified have been catalogued and computerized. Periodically this database of technologies will be updated as new products are introduced on the market. A pamphlet is being completed for use by older persons and their family members which describes methods for accessing technology and improving safety in the home.

An initial draft of the criteria for evaluating medicine organizing/dispensing devices has been completed. This draft will be reviewed by groups of older individuals with a range of disabilities, and revised based on their input. Currently, manufacturers of several medication organizing/dispensing devices are being contacted regarding their participation in the study. Older individuals began evaluating the products at the end of the year.

[156] Rehabilitation Engineering Center for Assistive Technology and Environmental Interventions for Older Persons with Disabilities

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Sponsor: National Institute on Disability and Rehabilitation Research

Purpose—The University at Buffalo was funded by the National Institute on Disability and Rehabilitation Research, U.S. Department of Education, to establish the Rehabilitation Engineering Center on Assistive Technology and Environmental Interventions for Older Persons with Disabilities (REC). The REC is operated in collaboration with the Consortium of University Hospitals and other local and state service agencies. An eight-member Board of Managers directs the REC's activities with policy-level guidance from Consumer and Institutional Advisory Boards. The Board of Managers represents the disciplines of Augmentative Communication, Allied Health, Architecture and Planning, Engineering and Applied Sciences, Geriatric Medicine, and Rehabilitation Medicine.

The REC is developing and disseminating products and information on assistive technology and environmental interventions. It is addressing the

diverse needs of older persons with disabilities, including persons with disabilities associated with the aging process, disease, or trauma, as well as older persons with developmental disabilities or mental illness, and special populations such as older persons in racial, ethnic, and economic minorities, and older persons in rural areas. The REC considers the needs of family members, elderly spouses—and other professional and nonprofessional caregivers of older persons—especially caregivers who are elderly. The REC is evaluating the assistive potential of low technology and high technology devices, exploring the environmental context in which older persons with disabilities apply technology, and improving the public and private sector systems delivering assistive technology services.

The REC has three Research Programs and three Dissemination and Utilization Programs. The three research programs represent the main elements

of assistive technology utilization: 1) Consumer Assessments—assessing the abilities and needs of older persons with disabilities and their caregivers; 2) Environmental Design—the physical context in which consumers function; and, 3) Assistive Technology—developing and evaluating devices for retaining or regaining functions. The three Dissemination and Utilization Programs are organized around

the main elements of assistive technology service delivery: 1) Device Utilization—training on assistive devices for older persons and their caregivers; 2) Professional Education—for physicians, nurses, therapists, counselors, product developers, and researchers; and, 3) Reporting and Technical Assistance—to consumers, service providers, and researchers in the field.

[157] Long-Term Antidepressant Use: Affective/Cognitive Effects

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Purpose—The long-term objectives of this study are to examine the efficacy of particular antidepressant strategies in minimizing recurrence rates of depression and to explore possible associated side-effects of these treatments in a geriatric population. Several critical areas of geriatric depression will be addressed, namely: (a) Is chronic antidepressant prophylaxis (beyond 20 weeks) necessary in geriatric patients who have recovered from an acute depressive episode? (b) Does chronic tricyclic maintenance therapy decrease recurrence rates in geriatric depression? (c) Does Li⁺ maintenance decrease recurrence rates of depression in the elderly? (d) What are the medical and neuropsychological sequelae of chronic Li⁺ prophylaxis in the elderly? (e) What concurrent medical conditions and medications interfere with the effectiveness of the antidepressant strategies under study?

Methodology—All patients over the age of 60 will be given extensive medical, neurological, laboratory, neuropsychological, and psychodiagnostic evaluations. Patients meeting diagnostic criteria for major depression will be treated in a standard fashion with the tricyclic nortriptyline (NT). After a stabilization period of 20 weeks on NT alone has been achieved, patients who have responded to treatment and are considered in remission will then be randomized to receive: 1) placebo with gradual discontinuation of NT; 2) maintenance NT alone; or, 3) maintenance Li⁺. Patients in each group will then be followed for a period of two years and monitored for recurrence of their depressive disorder. In addition,

possible side-effects associated with long-term use of lithium or NT will be closely monitored through periodic assessments of serum levels, clinical status, self-reported complaints (as measured by a side-effects checklist), and neuropsychological functioning. An attempt will be made to determine which side-effects are most prevalent, most bothersome, and most likely to lead to noncompliance.

A second component of the study will evaluate the prophylactic effects of NT or Li⁺ in recurrent depression in patients who have received ECT for medication-resistant depression. Patients will be offered ECT if they have not responded to NT after 4 weeks with a therapeutic serum level. Twenty weeks after ECT has been completed and patients are stable, patients will then be randomly assigned to maintenance therapy groups as outlined above. Patients will then be followed similarly to the patients in the first component of the study.

Progress/Results—Participants are actively being recruited into the study and neuropsychological medical examinations are underway for these subjects. Results are not yet available.

Future Plans/Implications—This study will evaluate the efficacy of using lithium to treat geriatric depression. Because of the major cost savings that would result if lithium would prove effective in decreasing the relative relapse rate in geriatric depression, it seems warranted to conduct systematic studies to explore this possibility.

[158] Attention in Early Dementia

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Sponsor: *Rehabilitation Research and Training Center on Aging*

Purpose—The purpose of this investigation is to: 1) study attention in two different diagnostic groups—dementia of Alzheimer type and vascular dementia; and, 2) study the relationships between attentional processes, learning, and memory in these populations.

Methodology—Experimental subjects are individuals who have a recent diagnosis of either early Alzheimer's disease or subcortical arteriosclerotic disease with dementia. Diagnoses are made based on results of laboratory tests, imaging, and neurological work-up. Control subjects are a group matched for age, education, and gender who do not have such diagnoses.

The study employs a comparison group design with 50 subjects in each of three groups: an experimental group with a diagnosis of Alzheimer's disease, an experimental group with a diagnosis of vascular dementia, and a control group without diagnosis of dementia. All subjects are screened for

conditions that might influence cognitive status, independent of the diagnostic condition.

Measures include several research and clinical neuropsychological tests of attention, learning, and memory: Biber-Glosser Visual and Verbal Supraspan Tests, tests contributing to the Attention Quotient of the Weschler Memory Scale, Digit and Visual Span Tests forward and backwards, Benton Figure Recognition Test, and "A" Cancellation and Line Bisection Tests of hemifield neglect. In addition, computer-assisted tests of several forms of attention are drawn from a package of tests developed by Denver Neuropsychological Consultants. They include: orientation to change, selective attention, divided attention, focused attention, and sustained attention.

Progress—To date, the procedures have been pilot-tested on 10 experimental and 10 control subjects. Data collection was completed this summer.

[159] Caregiver Health

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Sponsor: *Rehabilitation Research and Training Center on Aging*

Purpose—This study is investigating the physical and psychosocial health consequences on elderly individuals of providing care to their disabled spouses.

Methodology—Subjects are men and women over 55 years old who are married and living with their spouses. The study utilizes a comparison design with three groups: an experimental group of 30 caregivers of cognitively impaired spouses, an experimental group of 30 caregivers of physically impaired spouses, and a control group of 30 noncaregivers. Data on psychological and social health cover: 1) demographic factors; 2) the level of care provided by caregivers; and, 3) scores on scales of personal-

ity, social support, psychological distress, and perceived stress. Data on physical health are composed of quantified results from health history and a physical examination as well as scores on scales of physical symptoms and health locus of control.

Progress—The study has gone through design and pilot-testing phases, and data from 60 subjects have been collected. Preliminary data analyses suggest a general pattern whereby caregivers of cognitively impaired spouses report the highest levels of psychosocial and health symptoms, caregivers of physically impaired spouses report the next highest levels, and noncaregivers report the lowest.

Preliminary Results—The cognitive caregiver group had significantly high symptoms of depression, anxiety, and hostility, and the physical caregiver group were moderately high on depression and anxiety. Both reported somatic complaints. Both caregiver groups had the same number of identified stressors, which were 40% higher than the control

group. The severity of experienced stress was highest among the cognitive caregiver group. Cognitive caregivers reported 50% more current health symptoms than the control group, and physical caregivers reported 30% more. Overall, caregivers realized they were responsible for their own health, but placed the care of their spouses above their own health needs.

[160] Cognitive Beliefs in Caregivers of Persons with Dementia: Their Role in Stress

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Sponsor: Rehabilitation Research and Training Center on Aging

Purpose—It is well-known that caregivers of persons with dementia frequently experience high levels of stress, both physical and psychiatric. However, it is not well understood what contributes to this stress. It is only weakly correlated with measured dementia, needed assistance, and even behavioral problems. Factors intrinsic to the caregiver must also be examined.

The purpose of this research is to determine if extreme, unrealistic, and self-defeating beliefs play a significant role in creating stress. Persons, for example, who believe they should never get upset or should always do things correctly may be prone to physical and/or psychiatric symptoms of stress, since these conditions can never be met.

Progress—A 20-item Belief Questionnaire for caregivers was developed and refined. Items reflect extreme beliefs about caregiving and oneself, and self-evaluation of caregiving. The items were rated by experts and refined. Reliability (test-retest) is 0.82. The scale was given to 100 caregivers enrolled in an educational support group for caregivers of persons with dementia.

Other measures collected on the caregivers include self-appraised stress, recent medical problems, number and kind of medicines taken, Zarit's Burden Index, and the Yesavage Depression scale. Patient data included MSE scores (Folstein), Blessed-Roth scores, number of years of dementia, number of behavioral problems, and age. The results are being analyzed.

[161] DNR/CPR Discussions with Geriatric Inpatients: The Psychological Impact on the Patient

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Sponsor: Rehabilitation Research and Training Center on Aging

Purpose—A significant number of geriatric patients have strong positive or negative feelings regarding nonresuscitation following a cardiopulmonary arrest. However, many physicians are reluctant to discuss CPR or DNR issues with their older patients because they assume negative patient reactions. Some of these assumptions are: increased patient fear and anxiety, depression, suicidal ideation, and

patient concern that hospital care would deteriorate if nonresuscitation was desired. As a result, when a cardiac arrest occurs, physicians rely on themselves or the family to make life-or-death decisions which are not always in accordance with the wishes of the patient.

This study is investigating the psychological impact of discussing CPR and DNR decisions with

medically stable geriatric inpatients on a rehabilitation ward and encouraging them to make decisions for themselves.

Methodology—A randomized control group design was used, assigning patients to either a physician-initiated discussion of DNR/CPR or discussion of diet. Patients were assessed for depression, anxiety, death anxiety, hopelessness, and negative self-evaluation at three different time periods: a baseline data period, 24 hours following the discussion, and one week following the discussion.

Results—Data have been collected on 40 inpatients. Contrary to physician assumptions, CPR/DNR discussions were not associated with any negative psychological effects in the inpatients as measured by general anxiety, death anxiety, or depression.

Twenty-four hours following the discussion, the experimental group reported less depression or death anxiety than the control group, indicating that CPR/DNR discussions may help to alleviate feelings of depression or anxiety rather than instigate them. Feedback from the patients suggested that they welcomed an opportunity to discuss CPR/DNR with their doctor and to express their choice with physician input.

Future Plans/Implications—We hope to continue this study with 60 additional inpatients. The findings of this study suggest that CPR/DNR is not a fearful or anxiety-provoking topic for older adults as doctors assumed. Thus, we encourage physicians to actively involve their geriatric patients in life-and-death medical discussions and decisions, especially about CPR/DNR choices.

[162] Group Treatment for Depression in Older Persons: An Approach to Long-Term Improvement

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Sponsor: *Rehabilitation Research and Training Center on Aging*

Purpose—The objectives of this study are to: 1) test the effectiveness of a psychoeducational group treatment approach in treating depression and dysphoria in older persons; and, 2) determine if improvements in depression are related to improvements in activities of daily living and social activities.

Progress/Methodology—Seven 12-week therapy sessions were held involving a total of 44 subjects diagnosed as depressed using Research Diagnostic Criteria. The group therapy sessions combined cognitive-behavioral and expressive-emotive approaches. Questionnaires to assess level of depression, knowledge of depression, functional abilities, and patterns of family function were completed by the subjects prior to the group, and at six weeks, three months, six months, and one year after the

initial group session. Follow-up data are still being collected on the last group.

Preliminary Results/Implications—Preliminary results demonstrate a significant improvement in depression scores during the course of group treatment which is maintained up to one year following termination of group therapy. Further analyses are continuing. Conclusions of the study are as follows: 1) short-term group psychotherapy is effective in improving depression among older persons; 2) older persons with chronic disabling illnesses improved as much as older persons without disability; 3) gains achieved during treatment continued for up to six months later; and, 4) older persons, particularly with disabling conditions, may need periodic follow-up treatment in order to maintain treatment gains.

[163] Older Adult Health and Mood Index

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Sponsor: Rehabilitation Research and Training Center on Aging

Purpose—Measures of depression suitable for older persons, especially with coexisting medical problems, are few in number. Therefore, it is important to be able to separate various types of depression as well as their severity. Also, it is essential to distinguish patients who have medical problems presenting as depression, but who do not actually have true depression. The purpose of this research is to develop a screening instrument sensitive to the unique characteristics of older persons that will rapidly and accurately assess depressive symptomatology.

Results—The scale was constructed to follow the guidelines of DSM II and DSM III-R for depression. Half the items reflect mood disturbance (a necessary part of the definition), and the other half assess other depressive symptomatology (physiological, be-

havioral, and cognitive changes). Depression requires mood alteration plus at least six symptoms from the latter categories.

A 22-item scale was developed. It was subjected to expert ratings, refined, reworded, and administered to 100 patients. This version differentiated depressed and nondepressed persons on the basis of clinical rating and other measures of depression. It was then subjected to item analysis and cross-validated against psychiatric evaluations. Test-retest reliability was 0.87. Correlations with psychiatric evaluations were 0.80+.

The instrument allows five outcomes: normal, probable major depression, probable adjustment disorder with depressed mood, dysphoria, and medical symptoms of depression.

A technical manual on the scale will be available through the Research and Training Center.

[164] Personality and Health

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Sponsor: Rehabilitation Research and Training Center on Aging

Purpose—The purpose of this investigation is to study the relationships between personality factors and health outcome during aging.

Methodology—There were 144 participants in this study (67 males and 47 females); a longitudinal study of normal aging. All participants were healthy when they entered the study in 1980. At that time, they filled out paper and pencil questionnaires measuring personality (16 P-F, Cattell and Horn), social support (Interview Schedule of Social Interaction, Henderson, 1980), and Health Locus of Control (Wallston and Wallston, 1978). Each year they were given complete physical examinations, including laboratory tests, and their physical health was rated on a scale of 1 (excellent health) to 9 (very poor health), with a score of 10 indicating death at

that time. Results of this rating constituted data on health status. A repeated measures design was used with three points of health status measurement: 1980, 1985, and 1990. Results from the three psychosocial measures were used as variables to predict health outcomes.

Progress—All data collection has been completed and data analysis is under way.

Preliminary Results—Results of initial analyses are the following: 1) health declined significantly over time in the sample; 2) there were no sex differences in terms of health declines; 3) there were no age differences in health when change over time was controlled; and, 4) poor health outcomes were predicted by the following results of testing at an

earlier date when health was good: low availability and adequacy of social interactions, a dependent personality style, high anxiety, and a belief that personal health outcome is due to chance factors.

Future Plans—The following will be analyzed: 1) relationships that exist among various psychosocial measures; and, 2) disease types that are related to specific psychosocial variables.

VI. Head Trauma and Stroke

[165] Computer-Assisted Treatment of Hemi-Inattention in R-CVA Patients

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Sponsor: VA Rehabilitation Research and Development Service (Project #B610-RA)

Purpose—Patients with strokes involving the right hemisphere (R-CVA) have more accidents than all other rehabilitation patients. A primary risk factor for falls among R-CVA patients is hemi-inattention (i.e., neglect, hemispatial neglect), to left space. We also observed that falls during transfers and wheelchair navigation were the most common types of accidents reported for our hemi-inattending R-CVAs. In this study, we have developed techniques using a computer to train these subjects to compensate for neglect-related problems during simulated high-accident risk activities (i.e., wheelchair propulsion, transfers). We are investigating if such training will reduce their accident proneness.

Progress—All of our computerized tasks have been developed and have been piloted with a small group of subjects.

Methodology—Our subjects are wheelchair-bound, R-CVA patients who show hemi-inattention to left space. We will train the experimental subjects to sit at true vertical, systematically scan into left space, and scan while performing computer simulations of risky activities including propelling a wheelchair through a cluttered runway and parking a wheelchair for transferring to a bed. Computer simulation will be used so that training can begin even if the subject does not have the physical ability to transfer or drive a wheelchair at that time.

Our training will be initiated within the first 2 days of the subject's admission to the rehabilitation service in order to maximize its impact on other rehabilitation activities. The performance of the experimental group will be compared with that of a

group consisting of R-CVA patients who receive training to improve visual attention, but no training to improve scanning or other skills specific to neglect. These groups will be compared on the frequency of incident reports, ratings of accident proneness, and the progress of the subjects during rehabilitation therapies. In addition, we are assessing the generalization of training to other neuropsychological measures, and to a wheelchair obstacle course developed in our last study.

Results—During the time we spent developing the methodology for this study, we also conducted a study on predicting falls among a group of R-CVA subjects with neglect. We found that 47% of this sample fell during their inpatient stay. We also found that when hemi-inattention was present, the best predictor of falls was a fall questionnaire that sampled risk factors nonspecific to R-CVAs such as a history of previous falls, use of prescription drugs known for increasing risk for falls, motoric weakness, and general level of cognitive confusion. Also contributing significantly to the likelihood of falls was the subject's impulsiveness as indicated by his ability to inhibit certain behaviors until a signal was given.

Recent Publications Resulting from This Research

Predicting Accidents in Right CVA Patients with the Wheelchair Obstacle Course. Godlewski MC, et al., J Clin Exp Neuropsychol 12:73, 1990.

Prose Memory Deficits in Right CVA Patients. Webster JS, Godlewski MC, Hanley GL, J Clin Exp Neuropsychol 12:85, 1990.

A Scoring Method for Logical Memory That Is Sensitive To Right Hemispheric Dysfunction. Webster JS, et al., J Clin Exp Neuropsychol (in press).

[166] Hemi-Neglect Syndrome: Visual Scanning and Reading Skills Retraining

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Sponsor: VA Rehabilitation Research and Development Service (Project #C522-RA)

Purpose—The purpose of our study was to: 1) document the course of spontaneous recovery of left hemi-neglect (LHN) in right hemisphere stroke patients; 2) evaluate the sensitivity and utility of the Indented Paragraph Reading Test (IPRT) as a measure of LHN; and, 3) conduct a pilot study of perceptual remediation in patients who manifest chronic LHN (i.e., at least one year post-stroke).

Progress—We have completed our studies on the course of spontaneous recovery and the IPRT. One patient has completed the perceptual remediation training.

Methodology—*Study 1 and Study 2: Course and IPRT.* We examined 50 patients approximately four weeks post-stroke and again one month, 2 months, and 6 months later if, and only if, they showed evidence of LHN on the previous test occasion. The test battery consisted of five paper-and-pencil tasks which included line bisection, line crossing, cancellation tasks, IPRT, and Raven's Colored Progressive Matrices (RCPM). We developed six additional scoring variables for the IPRT which we believed would improve its sensitivity and discriminability.

Study 3: Perceptual Remediation. We identified a patient who continued to manifest severe LHN 18 months post-stroke. We first administered an extensive battery of neuropsychological tests. One of the authors (LP) then administered the computerized perceptual remediation training. Upon completion of perceptual remediation, the patient was again administered the battery of neuropsychological tests. The training tasks were different from the pre- and post-test battery of neuropsychological tests to enable us to assess the generalizability of the remediation program to other tasks.

Results—*Study 1: Course.* Forty (80%) subjects showed evidence of LHN on the initial testing. Due to high attrition from the study, we were unable to

retest everyone who met the criteria for reevaluation. We estimate that more than half of the patients who originally evidenced LHN spontaneously recovered within the first year post-stroke, with the majority of improvement occurring in the first few months after stroke. Among those who continued to manifest neglect, the severity of the neglect diminished in most cases. Persistence of neglect was related to severity of deficits at initial testing. These findings suggest that rehabilitation efforts aimed at neglect may not be necessary for all patients. Instead, methods of identifying patients who will manifest chronic neglect if not treated, and who will benefit from early intervention are needed.

Study 2: IPRT. Education was found to be an insignificant factor in IPRT performance and even patients with minimal formal education (e.g., completed only second grade) were able to complete the test. The original scoring system proved to be as effective in identifying LHN as any of the additional variables developed. In addition, the IPRT proved to be a sensitive measure of LHN because it accurately identified more patients with LHN than the RCPM which has been described as one of the most sensitive measures. The IPRT was also sensitive to the improvement in LHN during spontaneous recovery, establishing its utility for measuring an important aspect of neglect.

Study 3: Perceptual Remediation. The pre- and post-test data have not yet been formally analyzed. Preliminary analyses suggest that after about 6 months of perceptual remediation, the patient improved his visual scanning ability on the computerized tasks and his wife reported improved functioning at home. This case study suggests that efficacy of perceptual remediation is possible with patients who manifest chronic neglect.

Future Plans—We plan to enroll three additional patients in the perceptual remediation portion of the study.

[167] Cortical Auditory-Evoked Potentials and Behavioral Measures of Aphasia

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Sponsor: VA Rehabilitation Research and Development Service (Project #C493-RA)

Purpose—The purpose of the project is to examine hemispheric processing of language by stable and recovering aphasic patients by using late auditory-evoked potentials as direct electrophysiological measurement of hemispheric involvement.

Methodology—Subjects undergo a behavioral testing battery including the Porch Index of Communicative Abilities (Porch, 1967); the Boston Diagnostic Aphasia Examination Severity Index (Goodglass and Kaplan, 1973); a handedness questionnaire; and a bilateral hearing screening at 500, 1k, and 2k Hz. Evoked potential testing is made up of a right hemisphere task (music), a left hemisphere task (language), and a nondifferentiating task (noise). While the subject is actively involved in processing the information in the task, evoked potentials to irrelevant auditory probe tones are used as the measure of hemispheric involvement in the task. Measurements of electrical activity are bipolar from central midline sites as compared to temporal sites on each side of the scalp. Stable patients will receive this paradigm on two separate occasions, recovering patients will be tested longitudinally at monthly intervals.

Progress/Preliminary Results—To date, 12 stable aphasic patients and 10 nondisabled controls have been tested with the entire paradigm. Eight recovering aphasic patients are in the process of being run at appropriate intervals. Both nondisabled control and aphasic subjects are continually being identified and scheduled for inclusion in the investigation. The preliminary findings of the study imply that the right hemisphere is somewhat involved in language processing after stroke.

Four presentations based on the methodology and/or preliminary findings from this study have been presented. One at the Colorado Speech and Hearing Association Convention and three at the Clinical Aphasiology Conference.

Recent Publications Resulting from This Research

A Possible Explanation of Problem Solving Deficits Based on Resource Allocation Theory. Selinger M, et al., Clin Aphasiol (in press).

Assumptions Made by Evoked Potential Paradigms. Selinger M, Clin Aphasiol (in press).

Cortical Evoked Potentials and Aphasia: A Follow-up Case Study. Selinger M, Prescott TE, Clin Aphasiol (in press).

[168] Expanding Loose Training Alternatives with Response Elaboration Training

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Sponsor: VA Rehabilitation Research and Development Service (Project #C384-2RA)

Purpose—Response Elaboration Training (RET) is a "loose training" procedure that was designed to increase the quantity and variety of content words and communicative exchanges produced by aphasic individuals. In contrast to didactic treatment approaches in which clinicians preselect restricted numbers of specific target responses, the emphasis in RET is on shaping and chaining patient initiated

utterances into increasingly longer and more elaborate responses. The loosening of response parameters in RET allows increased response flexibility and novel responding and it encourages patients to assume the primary burden of communication during therapy. In this way, RET attempts to incorporate elements of naturalistic communication that have been shown to promote generalized responding.

The primary purpose of this project has been to examine the effectiveness and generality of RET for aphasia, while the primary purpose of this particular phase of the project is to develop and evaluate computerized versions of RET, and thereby evaluate stimulus and response parameters that affect generalization. Specifically, the following experimental questions are being investigated:

1. What are the relative efficacy and generalization effects of RET and didactic aphasia treatment programs for facilitating an increase in the amount of informational content (i.e., content words, novel content words, mean response length, etc.), produced by mild to moderately impaired aphasic subjects?
2. What is the relative effectiveness of RET's minimal context stimulus presentation as compared to contextual animated stimulus presentation for facilitating generalized improvements in verbal elaboration skills?
3. Does an RET format that restricts stimuli and patient responding to a controlled set of semantic relations (e.g., agent, action, etc.) facilitate generalized improvements in verbal elaboration skills?

Methodology—The effectiveness and generality of RET is being examined with a variety of single-subject experimental designs including multiple baseline-across-behaviors designs with a multiple probe component and combined alternating treatments—multiple baseline designs. Descriptive analyses have also been developed to examine qualitative aspects of patient responding and social validation.

Progress/Preliminary Results—Extensive time series data have been collected and analyzed for 15 aphasic patients and social validation data have been obtained for 10 matched normals. Results demonstrate that RET facilitates an increase in the amount and variety of informational content produced by aphasic patients. A moderate degree of generalization has been found to stimuli, settings, and

individuals. In addition, preliminary data on the relative efficacy of RET and didactic aphasia treatment programs demonstrated modest but relatively greater increases in informational content, variety, and generalization for RET-trained stimuli and conditions.

During the past year, an RET computerized animated treatment prototype was piloted and modified. While the initial version of the computerized RET program incorporated semiautomatic data collection for response accuracy and verbal reaction time, it became apparent that the program lacked sufficient control over stimulus selection, repetitions, and the sequencing of treatment trials. Therefore, a central command function is being developed to provide greater experimenter flexibility and control over these parameters.

Relatedly, preliminary data were reported for our examination of factors that may be predictive of generalization. Retrospective data from nine aphasic subjects revealed that pretreatment production of "novel content" was relatively more robust than other predictors of the degree of generalization that occurred following RET. These descriptive analyses will continue, along with our assessment and modification of the computerized treatment program.

Recent Publications Resulting from This Research

- Broca's Aphasia. Kearns KP, in *Aphasia and Related Neurogenic Language Disorders*, 1-37, L.L. LaPointe (Ed.). New York: Thieme Medical Publishers, Inc., 1990.
- A Qualitative Analysis of Response Elaboration Training Effects. Gaddie A, Kearns KP, Yedor K, in *Clinical Aphasiology*. T.E. Prescott (Ed.). Boston: College Hill Press, Inc., 1991.
- An Alternating Treatments Comparison of Loose Training and A Convergent Treatment Strategy. Kearns KP, Yedor K, in *Clinical Aphasiology*. T.E. Prescott (Ed.). Boston: College Hill Press, Inc. (in press).
- Measurements Predictive of Generalization of Response Elaboration Training. Yedor K, Conlon C, Kearns KP, in *Clinical Aphasiology*. T.E. Prescott (Ed.). Boston: College Hill Press, Inc. (in press).
- Methodological Issues in Aphasia Treatment Research: A Single-Subject Perspective. Kearns KP, NIH Monograph (in press).

[169] A Measure of Explicit and Implicit Memory Retrieval

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Sponsor: *Kenny R.E.H.A.B.*

Purpose—A memory test is being investigated which, in addition to immediate, delayed, cued, and recognition memory, incorporates stem completion priming (SCP), where a list of words is presented, and recall is primed by 3-letter wordstems of the targets. The completion of stems with target words (minus baseline) is referred to as a SCP effect. Research demonstrates that some patients who display profoundly impaired free-recall display intact SCP. This unique method of administration appears to measure words which remain lexically activated.

Progress/Methodology—We are currently collecting data on 150 controls—30 brain injury, and 30 stroke subjects. Variables include age, education, and predicted IQ. Hypotheses regarding correlations between scores and performance on other neuropsychological measures will be investigated.

The measure was developed using words derived from the presentation of 201 wordstems to 81 controls instructed to complete the stems with the first word that came to mind. From this data, 22 target words were selected. Eight were low-frequency words (chosen by less than 10% of all subjects), chosen from wordstems which possessed one word with a uniquely high completion rate (chosen by greater than 30% of all subjects—range: 32% to 75%). Fourteen target words were low-frequency words (chosen by less than 10% of all subjects), chosen from wordstems with uniformly distributed completion levels (no completion rate above 25%—range: 8% to 23%). Two target lists were derived, balanced as closely as possible on level of concreteness, imagery value, word length, resemblance of stem to a complete word (e.g., bal-ball), placement of vowel in stem (e.g., bal vs. bla), and

overall completion frequency of both target words and the highest frequency word completed by the target's wordstem. Ten additional words were chosen using a similar procedure to serve as filler words, two to appear as the first, and three to appear as the last words on each word list to control for primacy and recency effects. Pilot data suggested comparability for free-recall and priming potential between lists.

The measure is administered in the following manner: 1) List A is presented using two encoding tasks, one data-driven (spelling recognition), and one conceptual-driven (high-closure sentences with targets present); 2) free-recall for List A is measured; 3) the stem-completion task is presented as a "word skills" task—the subject must generate completions to stems as rapidly as possible (timed)—16 are stems of target words and 16 are stems of List B (randomized); 4) free-recall for List A is again measured; 5) List B is presented using similar encoding tasks; 6) free-recall for List B is measured; 7) cued-recall of List B is measured using target stems; and, 8) recognition is measured using 72 words—32 target words and fillers—32 semantic distractors, and 8 words with a uniquely high completion rate. Intratest discriminability is measured by asking the subject to identify on which list the word appeared.

Six basic scores and approximately eight research scores result. Basic scores include: two immediate recall scores (of List A and B); and one short-delay recall score of List A, priming, cued, and recognition score. Research scores include scores for intrusions, overlap between free-recall and priming, discriminability in recognition, and others.

[170] Stem Completion Norms for 201 Wordstems

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Purpose—A multitude of studies have been generated over the past ten years using stem-completion priming to investigate memory processing and lexical activation. Stem-completion priming involves the presentation of a word list (e.g., *motel*, *attack*) with recall being primed by the three-letter wordstems of the target words (e.g., *mot*, *att*). Unlike a cued-recall test, the priming section is introduced as a “new task,” and the stems, mixed with other stems, are presented with instruction to form the “first word which comes to mind,” beginning with each stem. The completion of stems with target words (minus baseline) is referred to as a stem-completion priming effect. Memory tests utilizing stem-completion priming often resort to frequency-of-use indexes to determine predicted completions. This is an adequate method in some cases, yet less desirable than using actual normative data. Likewise, this method does not discriminate those stems completed with a particular word with great frequency, from those stems completed with many words, none being particularly frequent.

Often stem-completion priming performance is judged against a baseline set of stem completions which are intermixed with the target wordstems. In such cases, it is vital to know whether the target words and the baseline words are actually equated in terms of frequency of completion. Graf and Williams (1987) made available stem-completion responses for 40 wordstems which could be utilized by test developers investigating wordstem completion. Their subjects were 100 undergraduates from the University of California at San Diego. Education and age may have an influence on stem completion. A stem completion measure may be invalid if developed with the norms and used with individuals of lower education, differing in age range from the average undergraduate, or in a hospital environment—a frequent user of memory tests.

Progress/Methodology—To address the above concerns, and to expand the normative data to include subjects common to a large urban medical facility, new norms were developed. The present study investigated the stem completion rates of 201 wordstems, each of which formed the beginning of at least eight English words. All subjects were inpatients at one of two Detroit Medical Center facilities. Subjects were given a sheet of paper with stems on them and instructed: “Each three-letter wordstem forms the beginning of several common English words. Please complete these wordstems with the first word that comes to mind. Please do not use proper names.” Once completed, all words were entered into a word processor. Spelling errors were corrected unless the subject incorrectly used one of the first three letters (e.g., for the stem *pel*—the word “pillow” incorrectly spelled as p-e-l-l-o-w), or if the word was unrecognizable.

A total of 81 subjects correctly completed the task. None reported a history of neuromedical conditions associated with cognitive decline. Subjects were broken into three age groups: 16-39 ($n=19$), 40-59 ($n=31$), and 60-90 ($n=30$) years of age. Education averaged 11.92 (range 8-16), 13.24 (range 6-24), and 11.33 (range 5-18) years respectively. Estimated IQ's averaged 97.19 (range 85.57 to 115.71), 102.55 (74.1 to 118.63), and 98.32 (range 73.75 to 119.01) for the three groups respectively.

As of this report, the stems have been analyzed with respect to frequency of completion both between and across age groups. Comparisons will be made between the three age groups of the present sample and wordstem completions. These completion frequencies will be published in the future: they are available from the principal investigator by contacting him directly.

[171] Characterization of Associated Postural Adjustments in Healthy and Hemiparetic Subjects

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Sponsor: Medical Research Council of Canada; Fonds de la Recherche en Santé du Québec

Purpose—The purpose of this project was to quantify and compare the contralateral torques generated at the hip during specific unilateral hip efforts in a group of normal subjects and a group of hemiparetic subjects. By analyzing these torques, it was possible to characterize the postural adjustments occurring contralaterally during ipsilateral static efforts in both groups of subjects.

Progress/Methodology—Two multidirectional dynamometers for the lower extremities were used to measure ipsilateral and contralateral torques at the hips. Subjects were seated with their lower limbs secured to the dynamometers. Strain gauges on the dynamometers permitted the measurement of forces exerted at both hips in all planes of motion. These gauges were interfaced with a desk-top computer used to calculate torque in real-time and to collect data. A video monitor was placed in front of the subjects and displayed the magnitude and direction of their effort. During the experiment, the subjects had to perform unilateral hip efforts in flexion, extension, abduction, and adduction, representing approximately 5% and 15% of their maximal voluntary contraction (MVC). The tasks were accomplished using both limbs. For hemiparetic subjects, only the tasks at 5% MVC were required when using their paretic limb. The contralateral torques at the hip associated with the unilateral efforts were measured and stored for each task.

Results—The contralateral torques occurring during the unilateral hip efforts were characterized for a group of 16 hemiparetic subjects and a group of 18

normal subjects. Results indicated that the contralateral torques generated were mechanically opposite in direction to the unilateral torque exerted in both groups of subjects. Furthermore, the magnitude of the contralateral torques increased with increasing levels of effort performed ipsilaterally. It is suggested that these torques were postural adjustments responsible for the stabilization of the pelvis. In normal subjects, the magnitude of the contralateral torques was not different between right and left lower extremity exertions. However, in hemiparetic subjects, during performance of the paretic limb the contralateral torques were significantly increased compared to those associated with non-paretic limb exertions. It was suggested that the contralateral torques were generated simultaneously with the ipsilateral torque using a feedforward mechanism. Based on these hypotheses, a neurological model was developed to explain the relationship between the ipsilateral and contralateral torques in both groups of subjects.

Future Plans—More experiments, using different torque levels, will be done to evaluate the relationship between ipsilateral and contralateral torque magnitudes. Also, the protocol will be modified to verify the hypothesis that the contralateral torques serve a mechanical purpose. This will be achieved by changing the length of, fatiguing and vibrating unilaterally, the muscles responsible of the moments. Furthermore, the delay between the ipsilateral effort and the contralateral torque will be quantified using a cross-correlation technique.

[172] Spinal Cord Injury and Traumatic Brain Injury Registries in the United States

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Sponsor: Michigan Department of Public Health

Purpose—Traumatic injuries to the brain and spinal cord have been described as the most catastrophic in terms of their human and economic costs. In 1985, the Centers for Disease Control (CDC) began to promote the development of surveillance systems for "sentinel injuries": injuries that are so devastating in their personal and social consequences in terms of pure numbers, costs, and outcome, that preventing them is an important national priority.

The U.S. Department of Health and Human Services' publication, *Healthy People 2000: National Health Promotion and Disease Prevention Objectives*, addresses several priorities specific to injuries including the reduction of nonfatal spinal cord injuries (SCI) and traumatic brain injuries (TBI). The development of effective SCI and TBI prevention strategies has been severely limited by a lack of adequate data on these types of injuries.

Progress/Methodology—The first step toward addressing these priorities is to develop standardized data collection systems for SCI and TBI at both the state and national level. In order to contribute to this task, we have been involved in an ongoing effort to determine the "State of the States" with respect to the existence and nature of SCI/TBI data collection systems. Information on currently existing statewide SCI and TBI registries has been collected, consolidated and disseminated via report distributions, presentations and publications.

Currently, 15 states have SCI registries, 12 of which have a legislative mandate for reporting. Twelve states have TBI registries, 11 of which have legislative mandate for reporting. Additional states have recently passed legislation for the formation of registries or are in the process of developing new systems.

Results/Implications—Information collected on existing registries includes: which states have registries; which are mandated by law; how long they have been in existence; who within the state administers them; for what purposes were they developed; what inclusion criteria are used, including specific information on case definitions, ICD-9-CM diagnosis codes, severity of injury, and catchment area; how data are collected, including who is required to report cases to registries, methods for reporting, and what time restraints are imposed; what type of data is collected, including descriptive information on the case, circumstances of the injury, hospital course and patient outcome; and finally, how the information collected is used.

The primary objective of this information gathering and dissemination effort is to build a network of information exchange among the currently existing registries and those persons interested in developing systems. This type of information exchange and cooperation among the state registry programs will promote efforts toward standardized data collection for SCI and TBI across states and on a national level.

Recent Publications Resulting from This Research

The Development of Registries for Spinal Cord Injury and Traumatic Brain Injury (Abstract). Harrison C, *Arch Phys Med Rehabil* 71:782, 1990.

Spinal Cord Injury Surveillance in the United States: An Overview. Harrison C, Dijkers M, *Paraplegia* 29:233-246, 1991.

State Registries Aid Planning for the Future. Harrison C, Community Integration, Rehabilitation Research and Training Center on Community Integration of Persons with Traumatic Brain Injury at the State University of New York at Buffalo, Newsletter, 1:(2), 1991.

Traumatic Brain Injury Registries in the United States: An Overview. Harrison C, Dijkers M, *Brain Injury* (in press).

[173] Establishing the Reliability and Validity of an X-Ray Measure for Shoulder Subluxation

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Sponsor: National Health Research and Development Programme

Purpose—This study tests the reliability and validity of an X-ray method of measuring shoulder subluxation. A total of 72 volunteers with cerebrovascular accidents participated in the study, half of whom had clinical subluxation and half had none. One single radiological view of the shoulder taken in a standardized position provides four measures of subluxation. Three of these four measures have proven reliability and validity. The construct validity analysis showed significant differences between the mean scores for subluxed and non-subluxed groups. The concurrent validity of the X-ray measures in relation to external clinical measures was moderate.

The specific objectives of the study were to test: 1) the reliability of the method in relation to two potential sources of variation (positioning the patient in a specially designed chair, and reading the X-rays to determine the degree of subluxation); 2) construct validity by testing the measurer's ability to discriminate between subluxed and non-subluxed shoulders; and, 3) concurrent validity by comparing

the X-ray results with those from the best of existing clinical techniques.

Methodology—Data were collected from 36 stroke patients who had subluxation on clinical examination and 36 who did not. Patients who did not have subluxation participated in the validation phase. Those with clinical subluxation participated in the concurrent validity and reliability phase.

Progress—The construct validity of the X-ray measures was supported by their ability to discriminate subluxed and non-subluxed shoulders. The concurrent validity of the X-ray measures in relation to three external clinical measures was moderate. There is an acceptable level of reliability of the three best measures when all sources of error are included.

Future Plans—This project will permit further research into the effectiveness of therapeutic interventions for subluxation including shoulder supports. It will also allow documentation of the natural history of shoulder subluxation in stroke patients.

[174] Orthokinetic Orthoses: Clinical Efficacy Study of Orthokinetics Treatment for a Patient with Upper Extremity Movement Dysfunction in Late Post-Acute CVA

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Sponsor: Orthokinetics Research Foundation

Purpose—This study investigated the efficacy of orthokinetic orthoses application for restoration of voluntary movement to the nonfunctional hemiparetic right upper extremity of a patient six years post left hemispheric hemorrhagic cerebral vascular accident (CVA).

Progress/Methodology—The patient had partial right elbow extension in the active range of motion (AROM) = 95 degrees to 70 degrees, which could

not be further restored to full-range AROM by conventional treatments of physical and occupational therapy. The two-stage treatment by application of orthokinetic orthoses to the patient's paretic upper extremity comprised first a single-subject time-series pilot study, followed up by a course of clinical orthokinetics treatment sessions of one hour each, administered twice weekly over 36 weeks, and designed on the outcome of the pilot study.

Results—The patient was a 60-year-old male with left hemiparesis six years post-CVA. An experimental orthokinetics treatment, of double-blind single-subject design, was administered to the upper extremity, comprising the time-series A1-C1-A2-B1-A3-B1-C2-A4-B2: A1 to A4 = nontreatment phases; C1 = placebo treatment phase; C2 = sham treatment phase; B1, B2 = orthokinetics treatment phases.

The application of orthokinetic orthoses was based on the rationale of the neurophysiological mechanism of orthokinetics treatment for muscle imbalance in paretic limbs, which utilizes the difference in elasticity between the active (fully elastic) and inactive (relatively inelastic) fields of the orthokinetic cuff, overlying respectively muscle agonist and antagonist, with resulting activation of the agonist. This mechanism proposes selective cutaneous stimulation of low-threshold, slowly-adapting mechanoreceptors (e.g., Merkel's disks) via excitation of α -motoneurons, and of γ -motoneurons by α - γ coactivation, with reciprocal inhibition of antagonist musculature(s).

During orthokinetics treatment, four orthokinetic orthoses (cuffs) were applied, two each on the patient's arm and forearm, positioned according to the rationale for activation of elbow extension. The treatments were administered to the patient double-blind. The outcomes were consonant with the described neurophysiological theory of the orthokinesis effect. Internal validity (cause-effect relationship) was tested by inclusion in the pilot study of nontreatment control phases, placebo treatment phase, and sham treatment phase, with the orthokinetics treatment phases in the single-subject time-series design. During baseline phases A1-C1-A2, AROM of the elbow was 25 degrees (i.e., no remediation occurred); in orthokinetics treatment phase B1, however, AROM of the elbow increased to 60 degrees, then regressed to 25 degrees in nontreatment phase A3; decreased to AROM = 5

degrees in sham treatment phase C2, regressed to 25 degrees in nontreatment phase A4, and increased to AROM = 65 degrees in orthokinetics replication phase B2. These outcomes were consistent with application of the orthokinetics treatments and hence supported its internal validity.

A clinical course of treatment for 36 weeks for one hour twice weekly followed the pilot study. The elbow AROM of 40 degrees, achieved during the pilot study, was subsequently increased to 135 degrees, with carry-over. Additional gains were demonstrated in active right shoulder flexion and abduction to 95 degrees each, and full range of horizontal abduction and adduction; active thumb abduction range 25 degrees to 50 degrees; lateral pinch of thumb to the second and third finger pads, and to the distal interphalangeal joint of the fourth finger.

Functional gains included the patient's ability to don and doff gloves on the right hand, and to feed himself independently with the right hand. The patient was also able to engage in pottery making. His functional control of the right upper extremity was restored to raise and shape pots bimanually on the potter's wheel, using the right hand assistively with light pinch of thumb and index pads. Work tolerance for pottery making increased to seven hours over the period from treatment week 15 through 36. The outcomes supported clinical efficacy of the orthokinetic orthotics intervention, as well as its internal validity (causality).

Future Plans—Future plans for the project include further investigations of internal, external, and clinical validity of orthokinetic orthotics treatment for paretic movement dysfunction of persons with stroke, and traumatic brain injury. These studies are part of an ongoing cooperative clinical trial on the utilization of orthokinetic orthotics in physical and neurological rehabilitation.

[175] Effects of Orthotic Positioning on Skilled Prehension in the Hemiparetic Hand

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Sponsor: *Rehabilitation Institute of Michigan*

Purpose—Return of hand function is believed to follow a predictable sequence after a cerebral vascular accident (CVA) resulting in hemiparesis. Recovery can stop at any stage, and research indicates that only 10 percent of the CVA patients admitted to rehabilitation facilities have regained functional use of the involved hand by the time of discharge. Many more patients, however, recover to what is known as Brunnstrom's Stage 4, in which they have some lateral pinch along with mass finger flexion and extension.

Splinting the hand to decrease spasticity and/or improve function in neurological conditions is controversial, and little empirical evidence about its effectiveness is available. There is some indication, however, that a splint which holds the thumb away from the palm can improve prehension in subjects who are hemiparetic due to cerebral palsy.

Therefore, this project is exploring the potential for using a short opponens orthosis with stroke patients to inhibit inappropriate/primitive patterns of prehension and facilitate more mature skilled prehension.

Progress/Methodology—Patients with adequate cognitive function to follow simple directions were referred to researchers by their occupational therapists when they recovered to Stage 4 in the involved upper extremity. The patients were screened and informed about the study. Those who agreed to participate were fitted with a standard short opponens splint. They performed a series of seven grasp/release tasks without the orthosis, then repeated them while wearing the orthosis. The tasks included parts of the Erhardt Developmental Prehension Assessment, as well as tests designed by the

researchers to measure prehension against resistance (e.g., compressing a putty pellet, pulling a cube attached to a spring).

Results—Twenty-seven patients (16 men and 11 women) participated in the study. Right hemiparesis was more common in the sample than left hemiparesis. The modal time between onset of the CVA and involvement in the research was three weeks.

The data collected for the project have recently been analyzed. Preliminary findings are: 1) the Developmental Prehension Assessment (which was standardized on neurologically involved children) is useful for describing subtle differences in the prehension patterns of adults with CVA; 2) patients accepted the splint and said they would follow a home activity program to improve prehension skills; 3) patients used more mature prehension patterns and sustained pinch against more resistance when wearing the orthosis; and, 4) in spite of the improvements in the quality of their prehension, patients' skills were not sufficiently increased in one trial with the orthosis to change the level of their performance in functional activities.

Implications—These results suggest the need for further research to investigate the effects of daily use of an opponens orthosis over time. Splinting may offer new hope for the stroke patient whose recovery has ended at Stage 4. By artificially advancing an immature prehension pattern, an orthosis could facilitate the use of the involved extremity as a capable assistant during productive and leisure activities at home.

[176] Clinical Assessment of Hemiplegic Gait Following Stroke: A Pilot Study

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Sponsor: *Scottish Home and Health Department*

Purpose—Our purpose was to develop and pilot-test a gait assessment form for recording the visual observations of clinicians on patients with hemiplegic gait following stroke.

Progress—A hemiplegic gait analysis form was designed and preliminary testing was carried out with physiotherapy lecturers at The Queen's College, Glasgow. This allowed us to correct some of the flaws in the form before it was piloted.

Methodology—Six hemiplegic patients were filmed walking along an instrumented walkway. Anteroposterior and lateral views were taken of their gait. These films were edited into short presentations and shown to three physiotherapists specializing in stroke rehabilitation who used the form to assess the patients' gait. Each physiotherapist assessed all six patients at both stages of recovery, and repeated the assessment twice more. The completed forms (108 in all) have been analyzed in terms of within-rater reliability, between-rater reliability, and validity.

Results/Implications—Within-rater reliability of the form is statistically significant for some raters and some individual form sections. Between-rater reliability is significant for some sections. A detailed analysis of these reliability statistics has shown which parts of the form have caused the reduction in

reliability. These are mainly sections which ask for judgments on severity or symmetry. Although raters were asked to indicate the presence or absence of an abnormality, rather than judge severity, some parts of the form do in fact force a severity judgment. These parts have been shown to be less reliable and will be altered for future trials.

There also seems to have been some confusion among the raters as to which side of a patient is abnormal. This may have stemmed from showing the patient walking in two directions, with the raters accidentally filling in the wrong part of the form, implying that the abnormality had changed sides. Also, the scoring system for the ankle/foot analysis is different from that for the rest of the form, and would have to be made consistent. It was also noted that the commitment of the individual raters made a difference to the reliability.

Validity is assessed by comparing the changes in speed, single-support symmetry, and step-length symmetry as measured by the walkway to the changes in the form scores from Walk 1 to Walk 2 for each patient. Again, some of the changes are statistically significant, and it is hoped that modifications to the form could improve this. The correlations between the change in walkway parameters and the change in form scores is no worse than the correlation between the changes in individual walkway parameters. Therefore, we have the basis for a valid, reliable method of visual gait analysis.

[177] Rehabilitation of Unilateral Neglect

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Sponsor: *None listed*

Purpose—The purpose of this research is to develop effective rehabilitation strategies for unilateral neglect.

Progress/Methodology—Single-case study designs, as well as experimental procedures, were used to evaluate the effects of contralesional limb activation on perceptual functioning among patients with

unilateral neglect. Three single-case studies found significant and generalized improvement in visual neglect as a result of inducing minimum left limb movement in hemiplegic or partially hemiparetic left-neglecting patients. Left limb movements were achieved in part via a "neglect alert device," a simple avoidance conditioning procedure which required the person to press a button with his or her left hand (if necessary with the help of the right hand), to prevent a loud buzz from emanating from the machine.

Results—Experimental investigation of one of the subjects suggested that the treatment of the three single-case studies worked because the left limb was moved in left hemispace: movements by the left limb

in right hemispace produced no significant reductions in neglect, and the same was true of movements of the right limb in left hemispace. The improvements in functioning were confirmed by ratings done by relatives, of everyday functioning (i.e., accurate navigation through doorways).

Future Plans/Implications—Currently, more sophisticated "neglect alert devices" are being developed in order to try to maximize activation of contralesional limb.

Recent Publications Resulting from This Research

Use of Left Versus Right Hand in Responding to Lateralised Stimuli in Unilateral Neglect. Robertson I, *Neuropsychologia* (in press).

VII. Independent Living Aids

A. General

[178] The "Responsive Environment": Needs Assessment and Planning

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Sponsor: VA Rehabilitation Research and Development Engineering Center (Core Funds)

Purpose—Finding a needed service is a problem anyone may face in an unfamiliar place. Discovering and learning to use resources in an unfamiliar setting is a particularly acute problem for those who require specialized resources to achieve functional parity in public and in the workplace. The "responsive environment" (RE) project is an effort to develop a system of communication aids which will guide the disabled user to disability-specific resources, using communication modalities appropriate to the user's disability activated only after automatically identifying the requirements of an individual. Making this interaction transparent or invisible to the user (i.e., without requiring any conscious action or inquiry) is a primary goal. Our intent is to develop a system that is adaptable to all types of disability: the RE would offer a blind person spoken messages, and visual guidance to a deaf individual.

Methodology—Initial prototypes of REs will be located at VA Medical Centers and will be adapted for visually-impaired and brain-injured users. The selection of these, out of the range of disabilities that could potentially be addressed, is based on the assumption that both groups would benefit from information presented in the appropriate form, but that the information formats and need for repetition (brain-injured persons presumably taking longer to become familiar with a new environment) would differ enough to provide a good test of the adaptability of the RE.

Another assumption is that a commercially available user-carried passive identification label, consisting of a credit-card-sized circuit which receives a radio signal and responds with a coded message, would suffice for automatic communication of user needs to the computer controlling an RE.

The present pilot project is to examine the above assumptions, as well as familiarize rehabilitation research and development researchers with similar work in progress elsewhere and with devices which could be integrated into an RE. Meetings are conducted with potential users to obtain input about their willingness to use an RE and the functions they feel should be incorporated. The desirability of a passive user-carried label compared to an active device that stores a greater proportion of the information otherwise placed in the RE computer will be explored.

Progress—Results of advisory group meetings have suggested that the RE should be a multicomponent system consisting of: 1) a user-carried identifier which might have more user-initiated command functions than the simple passive card; 2) an "entranceway," which first recognizes the user and includes a means for the user to select options through menus or a map display; 3) a series of interfaces at branch points along the user's path which provide additional information, perhaps verbally but also by nonverbal symbols; 4) a supervisory computer containing updated maps of the

environment and its occupants; and, 5) several levels of interface software, appropriate to first-time, though experienced, users.

An advisory group of civil engineers and architects is also being formed to determine how the recognition and communication devices of the responsive environment can be integrated into an

existing VA hospital for initial trial. Commercially-made transponders have been obtained so that a demonstration "environment" can be created, with voice, large-type text, or pictorial output from a computer being automatically selected using information encoded in the transponder.

[179] System for Integrating and Reporting of Occupational Therapy Functional Assessment (OT FACT)

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Sponsor: *American Occupational Therapy Association, Inc.; Apple Computer, Inc.*

Purpose—In 1985, the Standardized Assessment Committee of the American Occupational Therapy Association, along with the American Occupational Therapy Foundation, awarded two grants to begin the development of a profession-wide standardized assessment. The University of Wisconsin-Madison was awarded one of these. For the past four years, faculty and staff in several programs at the university—including University of Wisconsin Hospitals and Clinics, the Occupational Therapy Program of the School of Education, and the Trace Center—have been working on the development and testing of a functional assessment system.

As the development of the assessment progressed, it was renamed OT FACT (for Occupational Therapy Functional Assessment Compilation Tool). Results from preliminary testing indicated that a properly designed computerized version of OT FACT would greatly facilitate administration, scoring and charting of results. This would make testing of the assessment more accurate (by reducing the possibility of calculation errors), and could serve to increase the number of researchers and clinicians interested in and able to evaluate the assessment.

Progress/Methodology—OT FACT software has been completed and is now being distributed by the American Occupational Therapy Association. The software steps the user through the stages of the assessment, following the nodes of a decision tree. Scores are based on a simple trichotomous scale

(total deficit, partial deficit, no deficit), avoiding the complexity and inconsistency of graded scales. The program solicits scores from the user, tabulates and totals scores automatically, keeps records, and automatically charts results. The data synthesized presents a functional performance profile of the client which can be used to summarize the client's functional performance, to justify therapy plans, and to document the client's change in status over time.

Results—Revisions based on the beta testing of Version 0.9 of OT FACT were completed, and Version 1.0 was released by the AOTA in October of 1990. Validity and reliability studies of the new computerized OT FACT are currently under way at facilities around the country. In addition, occupational therapists in specialized areas of practice are being recruited as "upgrade consultants" for the planning of Version 2.0 of OT FACT. Development of a version for the Apple Macintosh computer is also being initiated. Research and development of OT FACT continues to be supported by the AOTA, with additional support from Apple Computer, Inc.

Recent Publications Resulting from This Research

Computerizing a System for Integrating and Reporting Functional Assessment. Smith RO, in Technology Review '90. Rockville, MD: American Occupational Therapy Association, 1990.

OT FACT Administration and Tutorial Manual. Smith RO, Rockville, MD: American Occupational Therapy Association, 1990.

OT FACT Scoring Guide. Smith RO, Rockville, MD: American Occupational Therapy Association, 1990.
OT FACT Version 1.0 (Computer Program). Smith RO,

Rockville, MD: American Occupational Therapy Association, 1990.

[180] Development of User-, Professional-, and Public-Accessible Databases

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Sponsor: *National Institute on Disability and Rehabilitation Research; Apple Computer, Inc.; IBM Corporation*

Purpose—One of the greatest obstacles to effective, widespread use of assistive and rehabilitative technologies has been the difficulty which consumers and service providers encounter in trying to find accurate and timely information about products and services. One practical solution to this problem has been to collect and centralize sources of information, allowing one organization to collect, organize, and update information and then make their information system available for general use.

Computer technology has been extremely useful in allowing storage and retrieval of these large quantities of information. However, due to the constraints of the technology at the time systems were first developed (the late 1970s and early 1980s), most large computerized databases were stored at a central location and accessed over the phone lines using a modem. Now, new technologies (including enlarged storage and memory, and compact disk read-only memory (CD-ROM) allow larger, more sophisticated databases to be stored on microcomputers—machines that are directly used by clinicians, educators, agencies, and individuals. The ability to place large databases on individual microcomputers: 1) allows database searching software to be made far more user-friendly for the novice; 2) allows inclusion of memory-intensive information such as graphics and sound; 3) eliminates on-line search time costs, which can be substantial; and, 4) permits the creation of access features for users with disabilities.

This new model of database access, then, is one of a distributed database network, with databases being distributed in their entirety on media such as

CD-ROM. Such networks complement (rather than replace) the existing centralized on-line networks.

Progress/Methodology—Development has been completed on one database (Hyper-ABLEDATA), and development of a second (Service Delivery Directory) is now under way. Database development work at the Trace Center addresses three needs: 1) the need for databases to be easy for novices to use with little or no training; 2) the need for the database user interface to be optimized for different types of impairments; and, 3) the need to explore how database distribution will work in practice.

The Trace Center is involved in both the design of databases for increased access and the establishment of distribution networks. The two databases which have been developed are: 1) Hyper-ABLEDATA, a comprehensive database of over 17,000 assistive technology products; and, 2) Service Delivery Directory, an information response and referral database structure meant to be used by different state or local groups to store and share service-related information. In the area of network development, the Trace Center has established CO-NET, a distribution system for CD-ROM databases.

Results—Hyper-ABLEDATA was first distributed on CD-ROM through CO-NET in the summer of 1989. The database CD-ROM is now updated and re-released every six months. The Service Delivery Directory was developed as a prototype, and is now being developed for actual use by state information and referral programs.

[181] User Needs Research Project: The Research and Training Center on Accessible Housing at North Carolina State University

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—The purpose of this program is to provide valid and useful information on the housing needs and characteristics of persons with disabilities that are related to the design, production, and consumption of accessible housing. The specific objectives of User Needs Research are: 1) to determine functional capabilities in the activities of daily living (ADLs) of persons of all ages with visual, hearing, mobility, and cognitive impairments; 2) to identify specific housing environment needs on the basis of functional capabilities in ADLs; and, 3) to identify groups of disabled individuals whose housing needs require further study.

Progress—The project is in its third and final year. Thirty-nine disabled individuals, including persons with visual, hearing, cognitive, physical and multiple impairments have been videotaped in their homes performing or simulating performance of a variety of ADLs. The videotapes have been analyzed to determine which activities are difficult for the participants and to evaluate the effect of the physical environment on ADL performance. In addition, a national survey of ADL task difficulty has been developed and pilot-tested.

Methodology—The project has made use of video-based observational methods to obtain detailed information about ADL task performance. It has used large-scale survey methodology to evaluate ADL difficulty and housing modifications among a large sample of persons with disabilities.

Results—The Center for Accessible Housing maintains a network of disabled individuals interested in housing environment issues. Presently, there are approximately 1,500 persons who have joined the Design Advisory Network (DAN) and completed the DAN questionnaire regarding ADL difficulties. Individuals with mobility impairment are well represented in the DAN, with sensory impairments being

less well represented. The most recent analysis of the DAN data reported ADL difficulty level by type of mobility impairment. The mobility impaired subgroups for this analysis were individuals with paraplegia, quadriplegia, hemiplegia, and amputated limbs. All groups rated house cleaning as at least moderately difficult. In addition, individuals with quadriplegia and hemiplegia had at least moderate difficulty with several other ADLs, including washing clothes, preparing meals, and bathing or showering.

The 39 individuals in the video-based case studies were videotaped as they performed or simulated performance of ADL tasks. Use of assistive devices, organizational strategies, assistance from others, and home modifications were documented. Analysis of tapes showed that visually impaired persons experienced difficulty with tasks such as adjusting the thermostat and operating a washer/dryer. Mobility impaired persons experienced difficulty with transfers to tub and shower, and hearing impaired persons had difficulty with the use of the telephone and doorbell. Older individuals, regardless of type of disability, experience greater difficulty than younger individuals. Ongoing analyses are examining more micro-level issues such as task demands for body movements and positional changes that create problems in ADL performance.

Future Plans/Implications—The national survey has been pilot-tested and was conducted in the fall of 1991. Complete data analysis was available early in 1992. Additional projects related to evaluation of the housing needs of persons with disabilities will be developed.

Recent Publications Resulting from This Research

Housing Design and Disability: The Relationships Between Typical Design Features and Performance of Routine Activities. Sanford J, Connell BR, Long R, Proceedings of the Twenty-Second Annual Environmental Design Research Association Conference, 1991.

[182] Assessing Individuals' Predispositions to the Use, Avoidance, or Abandonment of Technological Assistance

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Sponsor: *National Science Foundation*

Purpose—A “participatory action research” (PAR) paradigm was used to guide this research. Consumers, rehabilitation therapists and rehabilitation engineers were asked to identify influences on the variable use of technological assistance, with particular emphasis on psychological and psychosocial incentives and disincentives. Since completion of the original study in 1986, many sociopolitical, legislative, technological, and economic developments occurred; a longitudinal study was designed to assess influences on technology utilization over time.

Methodology—Individuals with severe disabilities (four quadrant involvement due to cerebral palsy or a spinal cord injury) completed the Taylor-Johnson Temperament Analysis, Personal Capacities Questionnaire, and Inventory of Socially Supportive Behaviors. Participants were selected according to their degree of assistive device utilization and were interviewed/observed regarding how easily, comfortably, and effectively they operated their devices, and under what conditions and circumstances they experienced difficulties. Participants were assessed in 1986, 1988, and 1991, providing a 5-year profile of their changing perspectives, health/rehabilitation status, and use of technological and personal assistance.

Results—Technology use by an individual is dependent upon characteristics within four major influences: 1) the particular technology (e.g., design, service delivery); 2) abilities and personality (e.g., aptitudes, judgment, outlook, expectations); 3) nature of the disability (e.g., type, severity, age at onset); and, 4) psychosocial environment (e.g., support from family and friends, life experiences, training and education).

Future Plans/Implications—When variables within each of the above influences on device use are organized by category of technology use (optimal and partial/reluctant) and non-use (avoidance and

abandonment), individuals can be profiled according to the likelihood of device use at a particular point in time. For example, a person may appear a partial/reluctant hearing aid user as far as support provided by the Psychosocial Environment, but an optimal user according to the characteristics listed for Personality and Technology. Thus, the Psychosocial Environment within which the hearing aid will be used may require intervention before the person can gain maximum satisfaction and functional gain from it.

Several assessment instruments based upon the results (thereby being consumer-driven) have been developed and are being pilot-tested: 1) Assistive Technology Device Predisposition Assessment; 2) Educational Technology Predisposition Assessment; and, 3) Technology Overload Assessment. The instruments were created to consolidate the information, and can be helpful in: 1) documenting reasons for recommending, or not recommending, a particular device at a certain point in time for an individual; 2) identifying current incentives and disincentives influencing an individual's use of a particular assistive device; and, 3) decreasing premature or inappropriate device recommendations so that those individuals who can most benefit from devices will be the ones to receive them. Comparisons of initial and postintervention profiles can: 1) provide the rationale for funding training or another device; 2) demonstrate an individual's improvement in functioning over time; and, 3) organize information about the needs of clientele for a particular region or facility.

Recent Publications Resulting from This Research

- Assistive Device Utilization and Quality of Life in Adults with Spinal Cord Injuries or Cerebral Palsy Two Years Later. Scherer M, *J Appl Rehabil Counsel* 21(4):36-44, 1990.
- The Assistive Technology Device Predisposition Assessment. Scherer M, McKee B, *Commun Outlook* 12(1):23-27, 1990.
- High-tech Communication Devices: What Separates Users from Non-users? Scherer M, McKee B, *Augment Altern Commun* 6(2):99, 1990.

Matching People with Assistive and Educational Technologies: A Look at Two New Assessment Instruments. Scherer M, McKee B, in Proceedings of the 5th Annual Conference, Technology and Persons with Disabilities, H. Murphy (Ed.), 589-600, 1990.

The Development of Two Instruments Assessing the Predispositions People Have Toward Technology Use: The Value of Integrating Quantitative and Qualitative Methods. Scherer M, presented at the 1991 AERA Annual Meeting, Chicago, 1991.

Psychosocial Factors Associated with Women's Use of Technological Assistance. Scherer M, presented at the 1991 American Psychiatric Association Annual Convention, San Francisco, 1991.

Assistive Technology Use, Avoidance and Abandonment: What We Know So Far. Scherer M, in Proceedings of the 6th Annual Conference, Technology and Persons with Disabilities. H. Murphy (Ed.), (in press).

[183] Applications of Technology: A Multidisciplinary Consortium and Service Delivery Model

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Sponsor: Office of Special Education Programs, U.S. Department of Education

Purpose—This project seeks to develop viable ways to conceptualize, fabricate, deliver, and utilize individualized technological adaptations (assistive devices) that will compensate for significant skill deficits in people with severe and multiple handicaps. It seeks to demonstrate the: 1) impact that such individualized adaptations can make on a person's employment and community integration; 2) coordination of job development and placement efforts needed with low market demand and/or complex rehabilitation engineering projects; and, 3) usefulness of a community approach to coordinate the resources, roles, and expertise of many agencies and disciplines.

Progress/Methodology—Each year ten individualized adaptations will be completed with the intensive expenditure of engineering expertise, involvement of special education professionals and rehabilitation specialists. Additionally, 20 persons each year with less complicated technology needs will receive support from project resources. Thus, the employment and community integration of at least 90 persons with severe handicaps will be positively enhanced over the life of this project. All of the consumers who receive direct services will be either currently in, or in the process of, transitioning into a local rehabilitation/regional center system.

Three agencies that provide vocational rehabilitation and other services to adults with severe handicaps have participated in this project.

Each year, ten technology teams will be assembled and assigned to Individual Program Planning

(IPP) teams or counselors requesting assistance. These teams will be responsible for creating customized adaptations for the ten persons who are assessed to be the most needy. Finally, project resources will support the development of a minitechnology center that will coordinate the various demonstration, training, research, and dissemination activities.

Results—Major accomplishments of the first year include: 1) important linkages and referral information forms needed to solicit, screen, and begin the individualized adaptations established; 2) 28 projects with 16 requiring significant effort (engineering design, field evaluations, and redesigns) have been initiated; 3) 12 of the intensive adaptation efforts are directed toward adults and four toward children; 4) ten additional individuals have been identified as needing assistive devices with at least four of them likely to require intensive efforts; 5) approximately 11 special education teachers, two occupational therapists and physical therapists, six engineering students, plus various family members and adult providers have served on one or more of the Tech Teams; 7) various project team members have given over 30 presentations at national, state, and local levels; 8) participation at the Reauthorization of the Rehabilitation Act Working Conference in Washington, DC; 9) community volunteers are actively involved in three technical adaptation projects; and, 10) development of a local area network of computers at the minitechnology resource center is about 80% complete.

Future Plans—Our plans include refinement of operational and referral procedures to improve the coordination and communication between various components of the project. Upon completion and delivery of the customized adaptations, field evaluations, periodic follow-ups, and formal documentation of the outcomes will be performed. The project team will assist the integration of the persons and their adaptations into employment and community settings. Additional project resources and personnel will evaluate the completed projects in terms of the reasons for success or failure; coordinate with others involved in similar efforts; assist others seeking to replicate our effort; and disseminate the project's findings.

It is anticipated that the local computer network of the minitechnology center will become fully operational during Year 2. This network will smooth the involvement of community volunteers, improve the coordination of Tech Teams, and document the completed individualized adaptations with photographs, technical drawings, and summary descriptions.

Recent Publications Resulting from This Research

Programmable Interface Box for Switches. Szeto AYJ, Adcock JD, LaRue DJ, in Proceedings of the 14th Annual RESNA Conference, Kansas City, MO, 414-416, 1991.

[184] Applications of Technology to Enhance Quality of Life: A Multidisciplinary Consortium Approach

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Sponsor: Office of Special Education Programs, U.S. Department of Education

Purpose/Methodology—This 36-month project focuses on developing technological adaptations (assistive devices) that will compensate for significant skill deficits in public school students with severe and multiple handicaps. The project seeks to demonstrate: 1) the impact that such individualized adaptations can make on a student's quality of life and integration into school, work, and community environments; 2) strategies for establishing the relationship between functional curriculum and rehabilitation engineering; and, 3) a local community approach to coordinate the resources, roles, and expertise of many agencies and disciplines.

Under a cooperative effort between San Diego State University and the San Diego Unified School District, the project will provide individualized adaptations to students attending 30 integrated comprehensive school sites in the San Diego area. The adaptation projects will be directed to students who, with individual adaptations, could increase their participation and integration. Each year, ten technology teams will be assembled and given the responsibility for creating customized adaptations for ten students identified most likely to benefit from such an intervention effort. In addition,

project resources will be directed toward another 20 students each year whose adaptation needs entail a less intense level of involvement.

Project resources also will, in part, support the development and operation of a mini-technology center in order to coordinate the various demonstration, training, research, and dissemination activities of this project.

Progress—Major accomplishments of the first year include: 1) establishing important linkages and referral information forms (i.e., the infrastructure) needed to solicit, screen, and begin the ten intensive individualized adaptations; 2) partial to full completion of 31 technical adaptations; 3) coordination and involvement in tech teams by thirty special education teachers, six engineering students, and several OTs and PTs; 4) over 30 presentations made at the national, state, and local levels; 5) the active involvement of community volunteers in three technical adaptation projects; and, 6) the integration of a local area network of computers into the mini-technology center to store information about currently available assistive devices and to facilitate the monitoring and reporting of project activities.

The goals for Year 2 are to make the mini-technology center fully operational; enhance the active involvement of community volunteers; improve the coordination of tech teams; document the completed individualized adaptations with photographs, technical drawings, and summary descriptions; evaluate the completed projects in terms of the reasons for success or failure; coordinate with others involved in similar efforts; assist others seeking to replicate our effort; and disseminate via

formal forums (oral and written) the project's findings. This project is being closely coordinated with related projects and existing services to increase its impact and ensure its efficiency and longevity.

Recent Publications Resulting from This Research

Programmable Interface Box for Switches. Szeto AYJ, Adcock JD, LaRue DJ, in Proceedings of the 14th Annual RESNA Conference, Kansas City, MO, 414-416, 1991.

[185] Development of Rehabilitation Beds

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Sponsor: *None listed*

Purpose—Our purpose is to develop hospital beds suitable for patients undergoing rehabilitation. These beds will be quite different from conventional hospital beds which are designed for chronic-care patients.

Methodology—Since no suitable commercially available type of rehabilitation bed has been found, we

are investigating the feasibility of designing the bed ourselves, in an effort to match our desired criteria as much as possible. The bed would be designed and a prototype constructed, all within the Centre. Through an interactive design process, involving Nursing and Engineering staff, good success can be expected.

[186] Mobile Arm Support

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Sponsor: *The Rehabilitation Engineering Centre*

Purpose—This device provides a support for patients with reduced arm control through neuromuscular weakness, particularly in degenerative conditions (e.g., muscular dystrophy). The patient's arm is supported in soft slings above and below the elbow, allowing for free movement in any direction—the volume of space accessible limited only by the patient. The patient's arm is rendered weightless, and therefore requires virtually no effort to move. The device can be adjusted to suit the arm

weight of each patient individually. The benefits are in the area of patient independence, recreation, and vocational interests. The use of physiotherapy is also promoted.

Progress—The device has progressed from a laboratory prototype through production prototype to production. The units can be wheelchair-mounted or floor-mounted as a workstation. These devices are currently available to the public.

[187] Lifting Seat

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Sponsor: *The Rehabilitation Engineering Centre*

Purpose—This device assists patients in rising from a seated position to a fully standing position. The patient is supported on a seat base which remains horizontal until the standing position. The seat arm rests follow the movement, providing support when the patient is upright, and allows easy transfer to a walking frame if needed. The seat can be raised using an electric actuator, elastic cord, or an airbag arranged in a novel way, which reduces the pressure required, and also keeps the pressure in the bag almost constant throughout the lift. The airbag is inflated by a vacuum cleaner motor, but could be

adapted to run from a compressed air system supplying many seats, for example, in a nursing home situation. The lift is entirely patient-controlled and can be halted at any stage. A foot control will also be provided which will override patient control to assist caregivers when transferring.

Progress—The device has benefitted from an extensive design study by a local consultancy, resulting in ten production prototypes for patient evaluation. Several features of the seat are currently the subject of patent applications.

B. Robotics

[188] Development of a Vocational Training Facility for Quadriplegics

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Sponsor: *VA Rehabilitation Research and Development Service (Project #B635-DA)*

Purpose—There are over 67,500 quadriplegics in the United States today, with an estimated 2,400–4,000 new injuries resulting in quadriplegia each year. These injuries occur most frequently to young males, and they can expect to live a relatively normal lifespan. Of these individuals, less than 12% are employed. One reason for this is the difficulty severely physically disabled persons have in learning skills, not because the material is too difficult, but because physical access to and manipulation of these materials is impossible.

The Vocational Training Facility (VTF) Project is developing a self-paced curriculum to allow quadriplegics access to training materials to learn entry-level skills in desktop publishing and presentation. Using a multimedia approach, the VTF Project will combine videodisk images and footage with computer-aided instruction software to give students

an integrated learning environment. A complete array of adaptive hardware and software (head pointers, speech recognition systems, adapted trackballs, etc.) will tailor the workstation to the capabilities of each student. In order to address the manipulation needs of users, a desktop robot, DeVAR, developed over the past few years as part of the VA's rehabilitation robotics program, will let VTF students take their medication, handle mouthsticks, insert diskettes, eat lunch, and perform all required daily-living and vocational-support tasks to support an unattended 4-hour learning session.

Progress—The 3-year project began in January 1991, and has begun the transformation of DeVAR for VTF tasks. In addition, curriculum software design has been started, and recruitment has begun on a Task Force of local companies and associations

involved in software engineering, desktop publishing, and disability services. All computer access devices currently available on the market have been either tested or acquired.

A large number of training programs for desktop publishing and presentation has been evaluated, and contacts have been made with several companies to allow the use of materials in the VTF curriculum.

Preliminary Results—The VTF Project proposes an 18-month development cycle for the training, software, computer access, and robot aspects of the learning environment. All these areas are being pursued in parallel. A second 18-month cycle will involve the training of 20 high-level quadriplegics, with follow-up to aid in job placement. We are contacting local agencies to begin the recruiting process.

Implications—Severely disabled individuals such as high-level quadriplegics need an environment that

facilitates their access to information, especially to learn new skills. Using an integrated environment, with multiple means of gathering and processing information, combined with a manipulation system to handle all desktop needs, disabled students have a chance at competing with able-bodied students in the acquisition of knowledge.

Recent Publications Resulting from This Research

Clinical Evaluation of Robotics Technology for Use by Persons with Severe Physical Disabilities. Hammel JM, Van der Loos HFM, in Proceedings of the International

Conference on Rehabilitation Robotics, Atlanta, GA, June, 1991. Factors in the Prescription and Cost-Effectiveness of Robot Systems for High-Level Quadriplegics. Hammel JM, Van der Loos HFM, in Proceedings of the 14th Annual RESNA Conference, Kansas City, MO, 16-18, 1991.

Task-Specific Assessment of Robot Effectiveness: Enhancing the Independence of Quadriplegics in the Workplace. Van der Loos HFM, Hammel JM, Leifer LJ, in Proceedings of the International Conference on Advanced Robotics, Pisa, Italy, June, 1991.

Evaluation of a Vocational Robot with a Quadriplegic Employee. Hammel JM, Van der Loos HFM, Perkasie I, Arch Phys Med Rehabil (in press).

[189] Mobile Autonomous Robot Base for Rehabilitation Applications

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Sponsor: VA Rehabilitation Research and Development Service (Pilot Projects #B989-PA, #B990-PA, #B991-PA)

Purpose—Three pilot projects were performed to demonstrate and develop basic sub-systems needed for a general purpose mobile rehabilitation robot base. The ultimate goal of the research is to develop an autonomous mobile robotic base which can function both independently and interactively with a user. This base can then be used as a mobile platform for assistive devices such as computers, robotic arms, or many other technologies.

This pilot work was based in part on previous accomplishments in autonomous robot navigation from the University of Michigan Robot Systems Division. This initial work was performed using a Cybermation K2A mobile robot system, modified and enhanced by the Robot Systems group for autonomous navigation. The current pilot projects utilize a commercial Denning DRV-1W mobile robot, chosen for its functional similarity to the Cybermation robot.

Results—The first project, *High Speed Obstacle Avoidance*, entailed the implementation of an obstacle detection and avoidance system on the Denning robot. This system allows the robot to travel at normal walking speeds and automatically steer around obstacles in its path, with little or no slowing. This project demonstrated the portability of the obstacle avoidance algorithms between systems, as well as its flexibility to operate with different dynamic and sensing characteristics. In testing the navigation system on the Denning, it was discovered that sensor cross-talk could produce avoidance of "phantom obstacles" when sampling at high rates required for robot speeds greater than 0.6 m/sec. At slower speeds, sensor sampling rate could be reduced so that this phenomenon did not occur, while still allowing safe navigation. New sampling methods to significantly reduce sensor

cross-talk have been developed and are now being employed in ongoing activities.

The second project, *Global Travel*, entailed the implementation of both a global path planning and an absolute positioning system. These systems allow the robot to store information about the environment in a world model and then compute or plan optimal paths in order to navigate within this known environment. The absolute positioning systems allow the robot to determine its location within the environment, and was performed using an infrared (IR) beacon and detector positioning system (obtained from Denning). This IR system utilizes small, uniquely identifiable infrared beacons mounted in the environment and a direction detector mounted on the robot. Absolute positioning methods were developed which allows the robot to determine its location as well as its precession. This algorithm is based on triangulation and operates anywhere the robot has a direct line of sight to three IR beacons. The triangulation routine employed imposes few restrictions in the placement of beacons.

The global path planner was designed to calculate a series of via points for the robot to follow, with the obstacle avoidance routines controlling robot behavior between via points. The initial design of the path planner was modified as a result of test runs in terms of the via points that were generated to define the path. The modification entailed the identification of the "unpassed" via point which was closest to the target yet not obstructed by any obstacles. This eliminated a substantial degree of backtracking. One problem identified in this work dealt with the interpretation of "low probability" obstacles arising from sensor misreadings. While the local obstacle avoidance algorithms described above have methods for dealing with these misreadings, techniques for overcoming these false obstacles also had to be developed for the path planning routines. The basic method involved the iterative reduction of obstacle "certainty values" until a free path was

found to the desired target. Although this procedure also erased parts of legitimate obstacles, our research demonstrated that this was not a problem when combined with the local obstacle avoidance methods.

The third project, *Companion Tracking System*, entailed the design, development, and implementation of a nonphysical link between the mobile robot and a user companion. The goal of the companion tracking system is to allow the robot to autonomously follow the user (or even lead in some cases) and minimize the level of interaction required to accompany the user. The system design chosen for this system was based on the utilization of both the ultrasonic sensing system and the IR beacon positioning system used in absolute positioning. In this application, a beacon was attached to the companion. This allowed the robot to find the companion by looking for the beacon. The beacon can be quite small and incorporated into a belt or other garment. In the first prototype, the IR detector was mounted directly to the body of the robot. As a result, it was necessary for the whole robot to turn for the detector to track the movements of the companion's beacon. A second level design places the IR detector on a small platform on the robot which can be rotated independently of the base. With a fast stepper motor controlling rotation, the robot can then respond quickly to companion motion and keep the target beacon visually centered.

Recent Publications Resulting from This Research

- A Comparison of Grid-type Map-building Techniques by Index of Performance. Raschke U, Borenstein J, in Proceedings of the IEEE International Conference on Robotics and Automation, 1828-1832, 1990.
- Fail-Safe Features of a Mobile Robotic Platform. Jaros LA, et al., in Proceedings of the 13th Annual RESNA Conference, 291-292, 1990.
- Ultrasonic Sensor System for Mobile Robot Obstacle Avoidance and Navigation. Borenstein J, Levine SP, Koren Y, in Proceedings of the 1990 International Conference on Rehabilitation Robotics, A.I. DuPont Institute, 121-131, 1990.

[190] Design of a Low-Cost Robot Arm Suitable for Human-Touch Applications

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Sponsor: VA Rehabilitation Research and Development Engineering Center (Core Funds)

Purpose—The Palo Alto VA Rehabilitation Robotics Project has been using a PUMA-260 robot arm for the past 12 years. The cost of this industrial arm, about \$45,000, is in part due to the performance requirements of mainstream robot applications such as assembly line operations in the electronics industry. In order to bring down the cost of robotics technology for rehabilitation purposes, the single most effective measure would be to reduce the cost of the arm itself.

The Low-Cost Arm (LCA) Project has developed a set of robot specifications for robots in rehabilitation and human-service applications. The specification set is designed to open markets for robot designers interested in human-service applications.

Results—The PUMA-260 robot was chosen 12 years ago by the VA Project as being the best small, esthetic, safe, industrial arm available. Based on this experience, we conclude that certain specifications can be relaxed, while others need to be strengthened. For example, industrial qualities of robustness, reliability, safety provisions, and programming capability will be retained or enhanced, while high-speed, high-force performance will be limited. Existing alternatives to the PUMA-260 have been assessed in terms of performance, design specifications, robustness and cost.

[191] A Robotic System as a Therapeutic Tool

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Sponsor: National Institute on Disability and Rehabilitation Research; Del Harder Rehabilitation Foundation

Purpose—Almost all applications of robotics in the field of rehabilitation focus on the development of "smart aids" for individuals with severe limitations in upper extremity function, and are designed to mechanically assist with selected personal care or vocational tasks. This project takes robotics technology in an alternative direction: it is a long-term study that focuses on the development of a robotic system to be used as a clinical tool in occupational therapy. The aim is to develop and evaluate hardware and software that can be used by the therapist to provide consistent, repeatable and measurable inputs, and to monitor and record patients' responses/actions in detail sufficient to generate reports of initial status and progress. Applications aiming at testing and at treatment have been

developed, or are planned, for a variety of patient problems.

Progress/Methodology—In Phase 1, a robotic arm exercise system was developed to be used in the reeducation of upper extremity muscles in patients with a stroke. The system presents and monitors some of the "movement pattern" routines therapists use in treating these patients. The system hardware consists of the UMI, Inc. RTX robot, an IBM compatible computer, a Robot Monitoring System (RMS) and two sensor switches with an indicator light. One sensor switch is mounted on the end of the robot arm and the other is placed at the patient's side. The RMS, a custom-designed data acquisition board which resides in the control computer, moni-

tors and collects the switch information. The software consists of a database, exercise procedures, a report-generating procedure and a pattern creation procedure. The software was written in Pascal and the RMS software was written in assembly language. The database contains the pertinent patient information. The pattern creation procedure allows the therapist to create individualized patterns for patients.

The patient is directed to perform a given movement or task as prompted by the end-effector and "home" switch indicator lights. The robot arm moves to a point in space and the indicator light on the end-effector switch illuminates, indicating to the patient to reach and touch the switch.

A formal evaluation of this system was performed, using 11 therapists and 22 patients. The study indicated that the system is safe, accepted by patients and therapists, and seen by the latter as having utility. However, a number of additions and modifications were suggested.

In Phase 2, additional software needed for two vocational assessment applications was produced.

Future Plans—Development of additional modules, constituting a system for upper extremity coordination testing/treatment, is under way. Five different

tasks will be built and field-tested: tracing a pattern with a stylus, manipulating nuts and bolts, turning knobs and other devices, pushing switches and buttons, and independent finger manipulation. Task difficulty will be gradable in terms of speed of performance required, size of objects, distance of task to trunk, and orientation of task. Continuous feedback to therapist and patient will be provided. The tracing task, which is implemented on a Deeco touch-sensitive screen, is undergoing pilot testing. The upper extremity coordination system uses the UMI-RT100 robot, and instead of the custom-made RMS board, a commercially available microcomputer data acquisition and control board is used.

We also plan to redesign a robotic module for developing stroke patients' prehension skills, which was built earlier in the project. While the concept was very attractive to therapists, laboratory testing of the module indicated mechanical problems which made it impractical.

Recent Publications Resulting from This Research

- A Robotic System to Provide Movement Therapy. Erlandson RF, et al. Proceedings of the Fifth International Service Robot Congress, Detroit, MI, 1990.
- Patient and Staff Acceptance of Robotic Technology in Occupational Therapy: A Pilot Study. Dijkers M, et al. J Rehabil Res Dev 28(2):33-44, 1991.

[192] Human Machine Interaction via Transfer of Power and Information Signals

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Sponsor: *National Science Foundation*

Purpose—The aim of this project was to establish methods of design and control of machines that have stable dynamic interaction with humans via simultaneous exchange of both power and information signals. Orthoses are examples of self-powered machines that should be built and controlled for the optimal exchange of power and information signals with humans. The human wearing the orthosis is in physical contact with the machine, so power transfer is unavoidable and information signals from the computer help to control the machine.

Progress/Methodology—We have derived and ex-

perimentally verified the mathematical framework in controller design and human-machine physical interaction in the sense of transfer of power and information signals. General models for the human, the orthosis, and the interaction between the human and the orthosis are developed. The stability of the system of human, orthosis, and the object being manipulated is analyzed, and the conditions for stable maneuvers are derived. The trade-off between stability and performance is described.

To verify the theoretical analysis, we have designed and built a prototype orthosis (called extender in this research work). The input to the

extender is derived from the contact forces between the extender and the human. The contact force is measured, appropriately modified (in the sense of control theory to satisfy performance and stability criteria), and used as an input to the extender control, in addition to being used for actual maneuvering. Because force reflection occurs naturally in the extender, the human arm feels a scaled-down version of the actual forces on the extender without a separate set of actuators. For example, if an extender is employed to manipulate a 10 lbf object, the human may feel 1 lbf, while the extender carries the rest of the load. The 1 lbf contact force is used not only to manipulate the object, but also to generate the appropriate signals to the extender controller.

Results/Implications—Our experiments show that the controllers derived by this research work are robust in the presence of significant variations in the human arm dynamics. Our research work will serve as the basis in design and control of intelligent

prosthetic devices. The results of this research are being made public by the publications listed below. The publications have resulted in widespread exposure of these ideas to other researchers and engineers in industry.

Recent Publications Resulting from This Research

- Human Machine Interaction via the Transfer of Power and Information Signals. Kazerooni H, IEEE Transactions on Systems, Man, and Cybernetics 20(2):450, 1990.
- Stability and Performance of Robotic Systems Worn by Humans. Kazerooni H, IEEE International Conference on Robotics and Automation, Cincinnati, OH, 558, 1990.
- Theory and Experiments on Robot Compliant Motion Control. Kazerooni H, Waibel BJ, Kim S, ASME Journal of Dynamic Systems Measurements and Control 112(3):417, 1990.
- Dynamics and Control of Robotic Systems Worn by Humans. Kazerooni H, Mahoney SM, IEEE International Conference on Robotics and Automation, Sacramento, CA, 2399, 1991.
- On the Stability of the Constrained Robotic Maneuvers in the Presence of Modeling Uncertainties. Waibel B, Kazerooni H, IEEE Transactions on Robotics and Automation 7(1):95, 1991.
- Dynamics and Control of Robotic Systems Worn By Humans. Kazerooni H, ASME Journal of Dynamic Systems, Measurement and Control (in press).

[193] Robotics Simulation Research

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Sponsor: *Natural Sciences and Engineering Research Council of Canada*

Purpose—Computer simulation is being employed as part of our research on robotic systems for use by physically disabled persons. The advantages of computer simulations over bench models are the increased safety of the investigator and the ability to change parameters without rebuilding the hardware.

Methodology—A major area of research on robots designed for use by physically disabled persons involves making them safe for the user, for attendants, and for others. Our basic approach is to

improve safety by improving user control. We are investigating the improvement in user control which will be obtained by the use of the control strategy, "Extended Physiological Proprioception."

Progress—Work undertaken so far has involved the development of computer programs to give a 3-dimensional simulation of robotic systems. When this is completed, we will go on to the next phase which will involve performing several simulated tasks and evaluating the success.

[194] Rehabilitation Robotics Program at Applied Science and Engineering Laboratories

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Sponsor: *Nemours Foundation*

Purpose—The rehabilitation robotics program at the Applied Science and Engineering Laboratories is studying two aspects of robotics technology in rehabilitation. The first concerns the development of software and prototype hardware that will allow a person with a physical disability to access a number of potential robots. The second involves the development of improved interface methodologies.

Methodology—The rehabilitation robotics project has taken a liberal view of what constitutes a robot. Thus we are developing a simple "robot" that will achieve a functionality similar to that of a headstick or mouthstick. This allows integration of novel input devices that can use information from the robot such as the forces exerted by the robot on its environment. Two styles of input devices are under investigation. The first style is based on the extended proprioception philosophy that relates position and force of the input to position and force of the robot. This ensures the transfer of power as well as information signals between man and robot. The

second style is investigating configurable and flexible interfaces that are able to adapt to the abilities of the operator.

Results—We have completed prototype development on some initial components. For example, we have designed a single degree of freedom pneumatic joint that will allow the robot to have increased compliance. This joint will be used as a basis for a full design of a compliant robot and will also be used to study possible schemes for robot control.

A prototype of a three-axis, force-controlled joystick has been developed and can be used to operate an RTX robot. Work is continuing on a shoulder control for a robot that can be used to provide position and force information to the operator. Finally, a simple interface based on accelerometer information has been developed and will be used to collect data from people who have difficulty with computer access. These data will be used to study adaptable input methodologies.

[195] Rehabilitation Robotics/Man-Machine Interface Laboratory

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Sponsor: *Texas Department of Mental Health and Mental Retardation; National Aeronautics and Space Administration; Texas Advanced Technology Research Program*

Purpose—This research involves the development of a real-time, flexible control system for rehabilitation/assistive robots for use by disabled individuals. The control system is based on both voice recognition capabilities and an infrared sensor system placed within the robot grippers. This system is designed to augment menu-based, fixed-task robot functions by providing flexible motion and gripping controls for instances where preprogrammed tasks are inappropriate. This would include tasks that are not on the programmed menu or emergency settings where rapid, flexible controls are required.

Progress—The voice recognition system is based upon modified commercial systems, including those by Dragon Systems and Votan Voice Systems. Recent research in voice recognition for a disabled population has centered on the ability of such systems to recognize slurred speech common to many disabled individuals with poor motor and vocalization skills. In addition, several methods to analyze and subtract ambient noise have been studied in order to optimize the voice recognition system design. Methods to integrate a flexible, voice activation system into other menu-driven, fixed-task

systems have also been analyzed. The infrared sensor system has been designed and tested to provide automatic gripping of nearby objects. This function is elicited by a single voice command and produces a gripping function of both stationary and moving objects. A neural network control system is being analyzed to incorporate both voice and infrared data into a robot motion/gripper control scheme.

Results—The voice recognition system has been tested for a wide variety of speech abnormalities and accents. The commercially based systems have been modified to incorporate several speech classifications resulting from various disabilities. Several sources of ambient noise have been analyzed for amplitude and frequency content. Various electronic and computational noise cancellation procedures have been developed as integral components of the modified voice recognition system. The infrared gripper control system has been designed, constructed, and tested on several types of small robots. Initial tests have demonstrated the ability to grip objects several feet from the gripper for both static and moving targets. The gripper system consists of many infrared emitters and receivers that determine the location and range of the target, and controls

the robot motion and gripping function to grasp the nearest object.

Future Plans/Implications—The voice recognition component to the overall robot control system is to be analyzed for potential integration with existing fixed-task, preprogrammed robot controllers in development at other rehabilitation research centers. The infrared gripper system will be tested for a wide variety of ambient conditions including light, target color and shape, target motion, and range from target to gripper. A neural network control algorithm is being continually studied to optimize robot motion and gripping function. The overall goal is to develop a flexible control system which can serve as an adjunct to fixed-task systems. The flexible version is being developed to allow disabled individuals and their assistive robots to cope with emergency situations where preprogrammed tasks cannot provide adequate support.

Recent Publications Resulting from This Research

- Automated Grasping Aided by Optoelectronic Sensors. Etter BD, Duck MR, Seaman RL, *IEEE Transactions on Robotics and Automation*, 1990.
 Voice Controls for Manufacturing Environments. Etter BD, Miller GE, *Manufacturing Review* 2(4):242-249, 1990.
 Voice Recognition for the Man-Machine Interface. Etter BD, *Adv Bioeng* 1990.

C. Communication Methods and Systems

[196] Computer Keyboard Emulation Through Interpretation of Pointing Gesture

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Sponsor: Bloorview Children's Hospital Foundation; Natural Sciences and Engineering Research Council of Canada

Purpose—The purpose of this project is to develop a faster method for people to access a computer when they have motor control difficulties in selecting keys. The intent is to provide the computer with abilities similar to a human observer who watches another person, who has a physical disability, point to letters on a communication board. An experienced observer will often accurately predict letters

based upon hand movement as well as linguistic knowledge.

Progress—An experimental computer input system has been developed and tested. This system is modeled after the experienced observer and is able to: 1) monitor the user's hand position while moving across a letter board; 2) use statistical tables to

determine which keys are most likely to be selected next based on up to four previously selected keys; 3) learn about the qualities of pointing motions of a particular user over time; and, 4) use this information to reduce the effort required of the user to make a selection.

Methodology—A Robotrak Vision System (RVS) senses where the user is pointing on a letter board. A CCD camera combined with an infrared light source and image processing hardware determines the position of a specially coated marker which the user wears on a finger while pointing on a letter board. An IBM PS/2 is connected to the RVS and accepts a selection when the finger stays within the region of a letter for some dwell time. The computer adjusts the dwell times dynamically according to the likelihood of each letter's selection. Likelihood is affected by movement and previous selections. By reducing the dwell time for more likely letters and increasing it for less likely letters, the level of concentration required from the user is reduced.

Neural networks handle the processing of

movement information. There is a different neural network for each letter on the board. When the finger crosses into the region of a letter, the network for that letter is activated and it looks at the history of the pointing motion leading up to when the finger crossed into its region. It asks the question, "Is the marker stopping here or moving on?" Likelihood of selection is influenced by the network's estimation of the answer. Lexical probabilities are used to estimate likelihood also.

Results—Simulations of the system with the prerecorded pointing motions of an individual with spastic cerebral palsy indicate that there is potential for speed increase over past "dwell" systems. In this simulation, the system was able to eliminate the dwell time completely in roughly 50% of the selections with 97% accuracy.

Recent Publications Resulting from This Research

Dynamic Competition Selection Technique for Computer Access. Nantais N et al., in Proceedings of the 14th Annual RESNA Conference, Kansas City, MO, 157-159, 1991.

[197] A Blackboard Expert System Approach Toward Implementing an Adaptive Force Joystick Computer Input Device for the Tremor Disabled

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Sponsor: Easter Seal Research Institute, Ontario; National Science and Engineering Council, Canada

Purpose—The long-term goal of this project is to develop expert system software, called an operation assistant (OA), that will aid disabled persons to configure and maintain proper settings on their computer input devices on a daily basis. The short-term goal of the research has focused on developing an OA for tremor-disabled persons performing screen-based tracking tasks using a force joystick input device.

Various problems immediately become evident when considering what the OA has to "know about" in order to perform its adaptation function properly:

- Performance evaluation problem: assessing the performance of a human tracker in a clinical

setting is a major problem due to its subjective nature.

- Knowledge combination problem: the development of an OA will involve processing numerical data as well as processing linguistic data such as user and/or external observer comments/evaluations. How can the knowledge gained from the numerical data be combined with the knowledge gained from linguistic information to take full advantage of both kinds of information?
- User model problem: the OA must identify a model of the user that describes how changes in the input device parameters can bring about a desired change in tracking performance. What form (i.e., numeric, symbolic) will this user model take?

- **Adaptation problem:** given that a user model has been developed, the problem remains of performing the adaptive actions in a smooth and stable manner.

Progress/Methodology—A test environment has been established to study possible solutions to the four problems aforementioned. A conceptual model for an OA has been defined that consists of: 1) an assessment module; 2) a user modeling module; and, 3) an adaptation module. Currently the assessment module is under study and requires consideration of the performance evaluation and knowledge combination problems. The vagueness and imprecision involved in the performance evaluation problem is being approached from the perspective of fuzzy sets. Several different viewpoints of handling the tracking performance problem—knowledge sources (KSs)—are being used together in a blackboard expert system framework. Knowledge sharing between the various KSs can occur at different blackboard levels and between different combinations of KSs. The level at which the KSs share knowledge affects the degree of precision in the resulting performance evaluations. The KSs in use to date within the framework are: 1) time-domain system identification (TDSI); 2) frequency-domain system identification (FDSI); 3) conventional clinical tracking indicators (CCTI); and, 4) observations derived from human observers (HOs).

To obtain data for the expert system, a study was conducted of tremor-disabled persons and non-tremor persons performing a random step-tracking task with the force joystick. We are currently investigating: 1) the tracking performance of each subject from the perspective of each KS; and, 2) the representation of the assessment information at the various levels of abstraction that result when numerical information is combined with linguistic information.

A blackboard expert system implementation of the assessment module has been written in LPA MacProlog 3.1 using the FLEX 1.2 expert system toolkit. Numerical processing routines were written in Lightspeed Pascal 3.0 and linked into the blackboard as Prolog predicates. The expert system runs on a Macintosh IIx. The representation of the user's tracking performance consists of six blackboard levels. All assessment information is stored as units of information at the appropriate level, and

the linked units constitute the current best hypothesis of tracking performance. The bottom level is where the raw data collected from the joystick are temporarily stored. A new unit is placed on this level for each run of 32 targets completed by the user. The TDSI, FDSI, and CCTI knowledge sources trigger from new units at this level. The TDSI fits an autoregressive moving average (ARMA) model. The FDSI computes a power spectral density using the force information from the joystick in order to identify tremor frequencies and power levels. A transfer function model is also computed and the tracking performance is interpreted. The CCTI evaluates tracking performance by computing various measures. The CCTI, FDSI, and TDSI units are stored on the Numerical Assessments (by Run) level. New units appearing on this level trigger averaging KSs that average the results over several runs, if no trends are detected, in order to increase the sensitivity to change. The results are stored as units on the Numerical Assessments (by Gain) level. HOs who observe the tracking assess the performance using the tracking assessment language (TAL). These assessments are stored as ASCII text files and are read into the HO level by a KS that interprets the comments. New units of information appearing at the Numerical Assessment (by Gain) and the HO levels trigger a KS that performs a transformation into a fuzzy universe of discourse. The fuzzy set representations are stored on the expert interpretation fuzzy set sublevel. New units here trigger a KS that specializes in aggregating the assessments together using two different fuzzy aggregation operators to form a consensus opinion for each TAL category. The result is stored as a new unit on the consensus fuzzy set level. Lastly, new units appearing on either of the fuzzy representation sublevels trigger a KS that performs a linguistic approximation to form linguistic representations of the assessment, which are stored on the Linguistic levels.

Results/Future Plans—The study results have shown that each KS can evaluate tracking performance and determine joystick gains independently with varying degrees of success. The representation of the assessment is a viable one for detecting performance changes at multiple levels of abstraction.

The next step is to develop the user model module, consisting of user models at each abstraction level.

[198] Speech Recognition to Enhance Computer Access for the Functionally Nonspeaking

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Sponsor: Easter Seal Research Institute of Ontario; Hospital for Sick Children Foundation; Apple Canada Ltd.

Purpose—This project is investigating whether combining speech recognition with scanning can increase the rate of computer input for persons who are severely physically disabled and functionally nonspeaking. The following specific questions are being addressed:

- To what degree will the addition of speech recognition affect input rate and accuracy?
- How do physically disabled, nonspeaking children and young adults rank the ease of using scanning alone and using speech recognition combined with scanning? Which input method do they prefer?
- How do speech intelligibility, severity and type of dysarthria, and consistency and distinctness of utterances affect input rate and accuracy?
- What is the rate of improvement across the series of learning sessions?

Progress—Learning sessions and trials have been completed with four out of eight participants. A hybrid scanning and voice recognition system has been prototyped on a Macintosh computer using HyperCard and a Voice Navigator speech recognition unit. This system allows users to either scan through or directly select groups of items through distinguishable utterances, followed by items within the groups.

Methodology—Two conditions, each employing a different access technique, are being investigated. In the first condition, participants select from a matrix using their present mode of scanning and personal switch. In the second condition, participants can use either scanning or voice recognition at any stage in the selection procedure. For each participant, both conditions use the same visual matrix, vocabulary, and feedback. Precautions are taken to avoid bias of the vocabulary toward one condition. Individual matrices are designed for each participant based on his or her personal writing system. The chosen

words, phrases, or letters are placed into logical categories using classifiers familiar to the participant. Selected words are sent to a text window above the matrix. The participant is involved in eight learning sessions and copy-type tests for each condition.

The study employs a within-subject counterbalanced design with repeated measures with eight participants. Participants range in age from 5–28 years. Participants have at least 1 year of experience using scanning access systems. All participants are presented with both conditions and the order of the two conditions is counterbalanced across participants to control for order effects. Dependent variables include: 1) the net rate of input measured in correct entries per minute (a summary measure of rate and accuracy); 2) *post hoc* analyses of input errors; 3) ease of use rating by the participants; and, 4) personal preference rating by the participants.

Preliminary Results—Current results suggest that gains in selections per minute can be made using scanning combined with speech recognition even with a very limited set of discrete vocalizations (three to five). All four participants were able to enter text more quickly using scanning combined with voice recognition. The statistical significance of these findings is yet to be determined. As these results were evident from the first sessions onwards it appears that the additional learning demands of using two selection techniques were outweighed by the gains in efficiency.

Results from the remaining participants should demonstrate the effects that the number of discrete vocalizations have on gains in performance; preliminary results indicate that there is a positive correlation. Performance results from the remaining participants are required before any conclusions can be reached concerning the general application of these findings.

Recent Publications Resulting from This Research

Speech Recognition to Enhance Computer Access for Children and Young Adults who are Functionally Nonspeaking.

Treviranus J et al., in Proceedings of the 14th Annual RESNA Conference, Kansas City, MO, 308-310, 1991.

[199] A Taxonomy of Device-Independent Information to Provide Multi-Modal Computer Feedback

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Sponsor: Easter Seal Research Institute of Ontario

Purpose—Feedback from the computer about what the computer is doing is a critical component of the overall usability of a computer system. The goal of the project is to develop an approach whereby computer feedback can be matched to the needs of users with disabilities through multiple channels such as visual, auditory, and tactile modalities. Humans are able to use combinations of five modalities (hearing, vision, touch, smell, and taste) to receive and process stimuli and feedback from the environment. In contrast, computers can be characterized as “monosensory,” in that most of the information is conveyed through one main modality, the visual display terminal. This limitation excludes users who have visual impairments or who find visual feedback too complex or confusing.

Progress—A review of the literature has provided little insight into the extraction of information from computer displays. Much of the current research in rehabilitation engineering has focused on input systems. Less effort has been placed on how to tell the user what is going on with the machine (feedback).

Eight general information categories have been defined to describe information that is presented to the user by the computer. These categories (message, block, prompt, set of choices, cursor, alphanumeric, symbol, and graphic) were defined by examining current software such as word processors and extracting common information objects. All Windows 3.0 objects have been defined as a hierarchical

composition (taxonomy) of the eight categories. For example, a command button is composed of a prompt which in turn is composed of alphanumerics and graphics. Macintosh and Motif objects will also be described within this system. The final component of the model will be to define displays unique to communication aids, such as scanning arrays within this system, establishing a complete taxonomy and structure of feedback.

Methodology—Based on information gathered from the literature as well as an in-depth investigation of existing word processor systems, a taxonomy of feedback strategies is being developed. The taxonomy will provide standardized nomenclature as well as a structure of the various relationships between the different types of feedback available with these word processors. Smalltalk/V, an object-oriented programming environment, is being used as the development tool for the taxonomy and the model of the project.

Future Plans—Experimental analyses will be conducted at each phase of the project. A usability study of the proposed taxonomy will be performed with clinicians to ensure that relevant feedback situations are accommodated and that the terminology is acceptable. A prototype word processor will be devised from the model of modality-independent feedback followed by studies to demonstrate the appropriateness of the model.

[200] Effects of Communication Aid Outputs on Attitudes Toward Individuals Who Use Augmentative Communication and on Speaker Output Preferences

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Sponsor: Easter Seal Research Institute of Ontario

Purpose—The effects of the components that make up an augmentative and alternative communication (AAC) system on the attitudes and preferences of those who come in contact with the user of that system have received little attention. Of particular interest is the way in which an AAC user delivers a message to a speaking partner. Research has shown that the use of a voice output device has resulted in significantly better attitudes than has a communication board. Favorability toward the individual who used AAC increased with the sophistication of the communicative technique employed.

One purpose of this project is to determine if the attitudes of speakers toward AAC users differed as a function of the mode of output employed by the AAC user. The second is to determine which outputs speakers would prefer that AAC users employ during conversations with them.

Progress/Methodology—Ninety-six subjects, aged 14–68, with varied educational backgrounds, observed four adult female AAC users in natural conversation with a speaker. Users employed a RealVoice communication aid with one of three output modes—speech synthesis (SS), liquid crystal display (LCD), or a combination of SS and LCD—or an alphanumeric communication board (ACB). Each subject observed each user and each output in a counterbalanced study design. Following each observation, subjects were administered The Attitudes Toward Non-Speaking Persons Scale (ATNP). After the final observations, subjects were asked to rank the outputs for preference.

Preliminary Results—Multivariate, univariate, and *post hoc* analysis revealed significant differences ($p < 0.001$) among all of the outputs/ACB for ranking, with SS+LCD most preferred and ACB

least preferred. As expected, there also were differences in ranking related to the AAC users ($p < 0.01$). Significant differences in ATNP scores were demonstrated ($p < 0.01$), but these differences were related not to the output employed ($p = 0.10$) but primarily to the gender of the observer ($p < 0.01$) with females providing higher, more positive scores. Analysis of the ATNP by subscales indicated significant differences in the general evaluation ($p < 0.01$) related to gender, user, and age (all $p < 0.001$), with observers aged 30–39 providing lower scores than those in their 20s and 40s. No overall differences were observed in the interactive/affective scores ($p = 0.10$), though subjects aged 60+ scored higher than those in their 30s ($p = 0.006$). Correlations between rankings and ATNP scores were negligible (-0.03).

Future Plans/Implications—Statistical analyses are being conducted which apply more appropriate and sensitive analyses of variance models for measuring attitudes differences, and nonparametric measures for determining differences in preferences are being employed. However, initial results suggest that efforts to provide AAC systems that parallel “natural” verbal communication (SS alone) or provide extensive speaker involvement in message assembly (ACB) may not be necessary. Speakers overwhelmingly preferred outputs that provided high levels of intelligibility and redundancy over outputs that offered “normalcy” or speaker-AAC user cooperation in message assembly. The lack of output/ACB effect on attitudinal scores contradicts results of previous studies, as do the higher scores associated with females. Further studies that include AAC users with different ages, etiologies, and levels of severity and studies that measure attitudes in alternate ways are warranted.

[201] Development of a Universal Communication Aid: LUCY

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Sponsor: Innovative Research Programme/Aids for the Handicapped; Foundation OSKAR; Lions Club, Delft; Ministry of Social Affairs

Purpose—The overall purpose of this project is to develop and realize a universal communication aid for a broad class of disabled people, taking into account the deterioration of the users' abilities in certain progressive diseases of the human motor system. This system, called LUCY, functions as a replacement for a PC-keyboard and as a control device for a standard PC-printer or speech synthesizer.

Methodology—LUCY consists of a control panel with a height of 236 mm and a width of 282 mm, representing a character display and a matrix of 8×11 cells, each containing a photodiode and an LED indicator. LUCY can operate in two modes. In the first mode, the input device consists of a light pointer that can be mounted on a pair of spectacles. The light pointer generates a red spot on the panel, and the character is selected by exposing a cell for a user-adjustable time. The lightspot detection unit is sensitive only to modulated red light from the light pointer, so the system can be used even in a highly illuminated room. When activated, the LED will be switched on as a feedback to the user. In the second mode, the device can be used as a single-switch matrix communicator where the user sequentially selects a row of LEDs that light up one by one. After selecting a row, the LEDs in the row will light up one by one until a selection is made. The speed of presentation can be adjusted by the user. The

control panel incorporates a display buffer that enables the user to edit a sentence before sending it to the output device.

Progress—A series of 40 LUCYs has been manufactured and distributed. At the same time, the hardware has been redesigned to decrease production costs and increase the reliability. The input facilities have been extended to enable the use of a mouse or a trackball. Moreover, this latest version enables the user at any time to switch from one mode to another. This modification was made at the request of users who want to change the mode when they become tired. A series of 50 is currently in production.

Future Plans/Implications—The next step will be to extend LUCY with a wheelchair controller. Special sensors will be developed, together with the necessary signal processing software, to make optimal use of remaining motor functions of the wheelchair user.

Recent Publications Resulting from This Research

LUCY, a Universal Communication Aid. Goezinne J, Stassen HG, Visse JB, in Proceedings of the 1st European Conference on the Advancement of Rehabilitation Technology (ECART), Maastricht, The Netherlands, 30-32, 1990.

LUCY, a Universal Communication Aid. Visse JB, Goezinne J, Stassen HG, in Proceedings of North Sea Conference on Biomedical Engineering, Antwerpen, Belgium, 416-422, 1990.

[202] Automatic Abbreviation Generation

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Purpose—The goal of this project is to increase the communication rate of physically disabled individuals via abbreviation expansion. Currently, abbreviation expansion systems require the assignment of a

unique abbreviation to each word that its user abbreviates. The user must then memorize all of these assignments. Flexible Abbreviation Expansion, one application of Automatic Abbreviation Genera-

tion, seeks to eliminate these requirements. In this approach, the expansion system recognizes any well-formed abbreviation for a word, eliminating the need to define and memorize specific abbreviation assignments.

Progress—Automatic Abbreviation Generation is demonstrated with a prototype Flexible Abbreviation Expansion system implemented in C++. The prototype distinguishes among nine different rules that it uses to categorize the possible expansions of an abbreviation. It has been tested on vocabularies of up to 1,300 words. It is source-code portable between both Unix and DOS, and compiles under a variety of distinct compilers. The prototype generates all of the abbreviation information it requires and stores this in memory. Under Unix, it consumes as much memory as it needs. Under DOS, it is sensitive to the amount of available memory and restricts its generation accordingly.

Methodology—The expansion system reads the vocabulary that the user wishes to abbreviate, generates a table comprising all of the abbreviations that it expects to see from the user for each word in the vocabulary, and identifies the abbreviation rules that each of the abbreviations represent with respect to their word. The user is then free to enter any well-formed abbreviation for the intended word. The system looks up this abbreviation in the table of anticipated abbreviations and categorizes the possible expansions according to the rule that the abbreviation represents. For example, the abbreviation 'ab' is a truncation for the words 'absent,' 'abundant,' and 'abbreviation,' and is a strict-contraction for the word 'aplomb.' The list of words is then ordered according to preferences based on features of the word (e.g., its associated rule). The most likely expansion is taken as the word with the highest preference.

While of significant importance, the user interface is considered separate from the expansion

system. That is, the expansion system provides all of the possible expansions for an abbreviation, and the user interface determines how to report these to the user. This allows a wide variety of designs that can be tailored to any particular user. One possibility is for the interface to simply replace the abbreviation with the most preferred expansion. The user would then press a special *REJECT* key to get the next most preferred expansion.

Another possible design is for the interface to present a list of the most preferred expansions, from which the user directly selects the one intended. A third possibility is a mix of the two, where the expander replaces the abbreviation with the most preferred expansion, and presents a list of expansions if the user rejects it.

Results—The prototype demonstrates that an abbreviation expansion system can recognize well-formed abbreviations of words. This project is being continued by GMS Systems with a Small Business Innovation Research Grant from the Department of Education. The objective of this grant is to demonstrate the feasibility of using Flexible Abbreviation Expansion to enhance job opportunities. The grant supports the development of a more practical implementation that rates the possible expansions by the user's preferences, bases its information in a file rather than memory, and incorporates a user-interface that can support a wide variety of configurations such as those described above. Ultimately, the information used by the Expander is seen to be included in a CD-ROM language module having an on-line dictionary or encyclopedia.

Recent Publications Resulting from This Research

- Automatic Abbreviation Generation. Technical Report 92-01. Stum GM, Dept. of Computer and Information Sciences, University of Delaware, 1991.
- Automatic Abbreviation Generation. Stum GM, Demasco PW, McCoy KF, in Proceedings of the 14th Annual RESNA Conference, Kansas City, MO, 97-99, 1991.

[203] Development of an AAC Software Architecture

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Purpose—The goal of this project is to facilitate more cost-effective development of augmentative and alternative communication (AAC) software by developing a general framework for describing AAC systems and a supporting set of tools that will allow developers to produce new applications. This will effectively minimize the duplication of efforts in a field where resources are precious and promote sharing of ideas and software among developers. By utilizing object-oriented software technology, it is possible to develop a set of building blocks that can be used to realize this goal.

Methodology—The use of object-oriented analysis, design, and development provide significant advantages toward reusable software. Specifically, we have chosen the C++ language for its support of the OOP paradigm, its efficiency, and its wide availability in the marketplace.

Progress—We have previously reported the development of a model that is comprised of two major components. LASO (Library of Adaptable Software Objects) is a collection of C++ class hierarchies that represent AAC functional components. Adapt is an interpretative authoring language based on

LOGO which is used to define object connections, provide functionality to vocabulary items (e.g., speak a message) and allow the development of high-level scripts that could be used in a variety of situations (e.g., instructional sessions).

Progress over the last year has been made in all areas of design and development. We have devoted much time to issues involving portability among different hardware platforms and operating environments. We have also modified some of our class interfaces to be compatible with the work of the ComSpec group in Europe who have similar project goals.

Future Plans—Over the next year we hope to complete a version of the software architecture that we can share with other developers. This will include completion of example modules of all of the class hierarchies, incorporation of language primitives into Adapt, a port of the software to Microsoft Windows, and user documentation.

Recent Publications Resulting from This Research

The Design of a Device Independent Screen Class for Augmentative Communication Software. Demasco P, Ball JE, Dunaway J, Bradley W, in Proceedings of the 14th Annual RESNA Conference, Kansas City, MO, 210-212, 1991.

[204] Compansion: A Technique That Applies Natural Language Processing to Augmentative Communication

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Purpose—The goal of this project is to increase the communication rate of physically disabled individuals via natural language processing techniques. We have developed a technique called Compansion which takes as input a compressed message (i.e., uninflected content words) from the disabled individual, and generates a syntactically and semantically well-formed sentence. At the same time, we

wish to do this by placing as little a burden on the user as possible. Thus, we are not interested in a simple coding system where sentences have been stored and are indexed by their content words.

Progress—The present system has a vocabulary of over 1,000 words. It handles most tenses, produces a variety of sentence constructions, and has the

capability to infer the verb or subject in some situations. The structure of the semantic parser has been radically overhauled. It now relies on a much more flexible knowledge structure than the template matching that it previously employed. In addition, a new version of the generator is being employed which provides a greater number of possible sentence constructions.

Methodology—Input to our system are the uninflected content words of an utterance; thus, many function words such as determiners (e.g., the, a) and prepositions (e.g., of, in) will be left out. The system is responsible for filling in missing words as well as correctly conjugating the verb and forming a syntactically correct utterance. We attempt to form an utterance whose word order most closely reflects the word order given in the original input. For example, if the system is given "APPLE EAT JOHN," we would like the system to produce the sentence, "THE APPLE IS EATEN BY JOHN." In order for the system to generate a well-formed utterance, it employs a semantic parser to form a semantic representation of the input words. In this example, the parser recognizes that EAT can be a verb which prefers an animate ACTOR and an inanimate/food OBJECT in order to correctly infer the semantic relationships between these input words. The resulting semantic representation (along with a specification of the original word order) is

then passed to the translation component. The translator is responsible for enhancing the semantic terms with language-specific information and converting them into a representation format compatible with the final phase of processing, a sentence generator. The generator attempts to form a syntactically correct sentence that retains the general order of the original input words (if possible).

Results—The system is much more robust. As well as being generally more flexible, it can now gracefully handle unknown words, and even make a reasonable attempt at determining the meaning of the unknown word from the surrounding words. Areas for further improvement include developing a syntactic preprocessor that will determine modification bindings as well as determining the scope of conjunctions by examining the order of the input. Also, we intend to allow for more complex sentence constructions, make use of discourse information, and we are continuing our collaboration with Semantic Compaction and Prentke Romich to transfer this technology into a "scaled-down" system. In addition, we are working on expanding the coverage of the system to include metaphorical expressions.

Recent Publications Resulting from This Research

Knowledge Representation Considerations for a Domain Independent Semantic Parser. Jones M, Demasco P, McCoy K, Pennington C, in Proceedings of the 14th Annual RESNA Conference, Kansas City, MO, 109-111, 1991.

[205] Enhancing Picture-Based Communication via Computer-Assisted Design and Instruction

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Sponsor: *National Institute on Disability and Rehabilitation Research; Nemours Foundation*

Purpose—There are many individuals who cannot benefit from picture-based instruction and augmentative communication interventions because their cognitive skills are not sufficiently advanced to permit understanding of pictured information. There is evidence, however, that we can advance the ability of an individual to understand two-dimensional representations through the application of systematic training procedures. Thus, a system that is capable of manipulating the size, color, and

quality of graphic representations can be used to generate stimuli, which in turn can be incorporated into a sophisticated training paradigm based on proven instructional principles.

Progress/Methodology—The system specifications are under development. This research will develop and evaluate a computer-based system for the generation and manipulation of pictures at a variety of representational levels. It will permit capture and

display of realistic, full-size, full-color images essentially identical to their three-dimensional counterparts. Because the system will be capable of manipulating the size, detail, and color of graphic representations, it will be used to assess the abilities of an individual at all levels of representation and to

train these individuals to comprehend increasingly abstract representations. An authoring system will permit interventionists to customize the applications they develop, and sophisticated instructional strategies will be incorporated into the software to maximize its potential as a training tool.

[206] Personal Computer-Based Augmentative Communication Systems

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Purpose—The purpose of this project is to develop prototype personal computer-based augmentative communication systems and transfer those systems, when appropriate, to the commercial marketplace.

Progress/Methodology—Development of a software-based communication system named Meta4 is nearing completion. The Meta4 package consists of a main program, which turns any PC into a dedicated augmentative communication device, and four supporting utilities that make Meta4 easier to set up and maintain. Progress in the last year has centered around the incorporation of graphics into the system and the completion of all parts of the package in preparation for transfer out of the laboratory.

Meta4 is designed for users with severe speech impairments in addition to physical disabilities. It is also designed for the user with visual and/or perceptual difficulties. With this in mind, much of the emphasis in developing the system has been on flexibility of system configurations and screen displays. This flexibility allows Meta4 to be set up, or configured, for each individual and changed to follow the needs of that individual. The system gives full control over the appearance of the display, including spacing between items on the screen, the

size and colors of those items, and how they are highlighted for selection. Full control is also available over how the system responds to the user. For example, the input devices and techniques, along with various timing controls, are all flexible and can be changed at any time.

There are four utilities that work with Meta4: the abbreviation/expansion utility, the vocabulary management utility, the configuration utility, and the usage analysis utility. Each has been designed for user-friendliness in order to encourage users to operate Meta4 to its full potential. Menu-driven displays and on-line help screens guide the user through the necessary steps to get the system operating as desired. The usage tracking and analysis aspect of Meta4 allows the clinician and user to get quantitative feedback on the efficiency with which Meta4 is being used, and the other utilities allow the necessary modifications to be made. With all the utilities, changes can be made at any time and take effect the next time Meta4 is used.

Future Plans—Communication is continuing with potential commercial vendors and work is being completed on each aspect of the system. It is anticipated that Meta4 soon will be commercially available.

[207] Speech Synthesis Program

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—The purpose of this program is to develop both the software and hardware for the production of high quality, highly intelligible synthesized speech with an unlimited vocabulary. Research in the program includes the development of a Spanish speech synthesizer and development of methods for customizing voices for each individual.

Methodology—The work in this program is based on diphone speech synthesis. Diphones are speech segments that run from the steady state of one phoneme through the transition between phonemes to the steady state of another phoneme. Because both diphone ends are at steady states of phonemes, diphones can be appended together to create any word or phrase. Yet, with only a limited number of phonemes in any language, the number of possible diphones is limited as well. So, using diphones, only a reasonable amount of memory is needed to create an unlimited vocabulary.

Diphones are obtained by recording a person saying words with the necessary transitions. The transitions are then extracted and stored in a library. A text-to-speech algorithm that converts text into its corresponding phonemic and then diphone representation is used to append the proper diphones together to create speech. Very little analysis is done of either the original recorded word or of the diphone transitions. In this way, all of the qualities of the voice of the original speaker are retained. As a result, the synthesized voice created is human-sounding and recognizable as being that specific individual.

Through the use of an automatic diphone extractor, synthesized voices can be created that are tailored to each individual in an acceptable span of time. Anyone with reasonable control over the vocal muscles can be recorded. The automatic extractor will then extract the diphones from those recordings,

enabling the creation of a voice that sounds like that person.

To further extend the population being accommodated with the synthesizer, Spanish synthesized speech is also being created. Spanish uses a different set of phonemes and a different set of rules for converting Spanish text to speech. However, using the diphone method of speech synthesis, no other changes are necessary to create Spanish synthesized speech with the proper accent.

Work in this lab also includes the development of a hardware speech synthesizer. Currently, the hardware being used is a parallel formant synthesizer.

Results—Currently, work on a speech synthesizer with the voice of a child is being completed. Using the text-to-speech algorithm, the voice of the child is very intelligible and retains the childlike quality. The automatic diphone extractor is ready for testing. The inventory of recorded sounds, as well as the text-to-speech algorithm for Spanish have been completed, and words created from Spanish diphones have the proper pronunciation and are highly intelligible to those who speak Spanish. It is too early to tell whether the hardware parallel formant synthesizer will produce synthesized speech with acceptable quality.

Future Plans—Future plans include research into incorporating prosodic information in voices created, and development of tools for improving the robustness of the diphone method for all voices.

Recent Publications Resulting from This Research

Automatic Translation of Spanish Text to Phonetics Using Letter-to-Sound Rules. Trittin P, *Hispania*, 74:478-480, 1991.
Synthesized Spanish Speech Using Letter-to-Sound Rules. Trittin P, Foulds R, in *Proceedings of the 14th Annual RESNA Conference*, Washington, DC, 314-316, 1991.

[208] Decision Support in Transition Planning

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Sponsor: U.S. Department of Education

Purpose—Transitioning students with disabilities from school to a satisfying life in the community is a complex process. Managing the transition process is the prime responsibility of the local education agency (LEA). The purpose of the decision support in transition planning project was to determine if promising practices in transition exist, and if a computer-based expert system can manage the complex individualized transition planning process. Such an expert system would provide a mechanism to share existing, but scarce, knowledge in four LEA situations: 1) when an expert is unavailable; 2) when the performance of nonexperts needs to be assisted; 3) when the efficiency of the experts needs additional expertise; and, 4) when transition personnel needs to be trained to understand the expert's process.

Progress—The feasibility project identified and researched successful practices in school-to-life transitioning and what kinds of decision support is needed by practicing school-to-life professionals. A separate research effort evaluated expert software systems to determine how the required data could be successfully incorporated into a cost-effective, individualized expert system for use on a variety of levels by LEAs throughout the United States.

Methodology—The research group conducted surveys, interviews, and evaluations of existing programs in 50 states and reviewed over 200 published case studies on school-to-life transition practices, expert computer systems and special education

programs. Input was gleaned from all major stakeholders in the school-to-life transition process: state directors of rehabilitation, educators, parents, employers, students with disabilities, and LEAs. Measured against this information, commercially available expert systems were studied to determine which would provide the best capabilities for managing complex individualized transition planning.

Results—A survey of stakeholders substantiated that clear transition procedures are needed and that the individualized transition plan (ITP) and the individualized education plan (IEP) should complement each other and be specific as to content. The study also indicated that while some practices are deemed important, they may not be practiced by all students. The impact of decisions made by nonexperts on the lives of transitioning students can be tragic in terms of: 1) the cost to the individual in lost life or vocational opportunities; 2) the additional public resources consumed by the individual due to the absence of self-sufficiency; 3) the cost of the delay in receiving vital services; and, 4) the risk of an unsuccessful transition to life with its subsequent penalties.

The results indicated strong, broad-based support for the concept of an expert decision support system among transition professionals and transition stakeholders. The research group concluded that such a system is feasible in terms of meeting cost guidelines, technical requirements, and human needs, and has recommended development of a prototype.

[209] Pointing Device Study Series

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—Remote headpointers can provide rapid, low-fatigue interface methods for computers. Because of their relatively simple hardware designs, they can also be efficiently and economically manufactured. As a result, a number of different headpointing systems have been developed or are under development at the present time.

To date, there have been no cross-comparisons of these various devices. In addition, many individuals who can use a headpointer can also use other pointing systems. A comparative evaluation between headpointing techniques and other approaches is therefore also required.

Progress/Methodology—A research instrument has been developed for collecting data on input device operation performance. The instrument was put through evaluative and normative testing. These initial studies showed that a discrete movement target acquisition task based on Fitt's Law can be useful for evaluating and comparing headpointing performance.

The first studies in the series concerned the effects of gain on subjects' performances using headpointing and standard mouse devices. A Fitt's Law pointing task (like the one used in testing the research instrument) was used to measure performance. The studies approached the question of gain effects from three angles: 1) to determine how control-display gain influences performance using a head-controlled computer input device; 2) to compare relative sensitivity to gain between head-controlled pointers and standard hand-arm controlled mice, and also to examine optimal gain

across the two types of systems; and, 3) to investigate control-display gain interactions with other task factors including target width, movement amplitude, and direction.

Results/Implications—Ten subjects participated in the studies. The results indicated that gain had a significant effect on movement time for both types of pointing devices and exhibited local minimums. Use of optimal gain levels with the head-controlled pointer improved subjects' performance by more than 21%. The results indicated that optimal gain was more important for the head-controlled pointer than for the conventional mouse in terms of movement time.

Little data has been available previously concerning performance at sub-optimal gain, or specifying optimal gain for headpointing-controlled computer input devices. This data is important for designing computer interfaces that enhance performance for computer users who have upper-extremity movement impairments, and thus must depend on headpointing devices.

Future Plans—Now that the basic validity of the measurement has been established, the scope of experiments will broaden to include other operations involved in using a pointing-based input device.

Recent Publications Resulting from This Research

Gain Effects on Performance Using a Head-Controlled Computer Input Device. Lin ML, Radwin RG, Vanderheiden GC, Ergonomics (in press).

[210] Development of Extensions for Standard Computers and Operating Systems to Allow Access by Users with Motor Impairments

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Purpose—The most effective technique for providing access to computers for persons with disabilities is to have the computer designed in such a way that it is already accessible when manufactured. Not all adaptations for persons with disabilities can be built into standard computers. However, a wide variety of accommodations can be incorporated directly into the computer design. The purpose of this program is to develop simulations, demonstrations, or actual functioning extensions to operating systems which can be used to demonstrate to computer and operating systems manufacturers how their systems could be modified to make them more accessible.

Progress/Methodology—The Trace Center has worked on the development of six principal access features for computers, and worked for their adoptions as standard parts of computer operating systems: 1) *StickyKeys*: The capability to execute multiple key operations (such as Shift-key) with a single finger, headstick, or mouthstick; 2) *RepeatKeys*: Control over auto-repeat of keys, including the rate at which keys repeat and the duration for which a key must be pressed before the auto-repeat commences; 3) *SlowKeys*: Control over the amount of time a key must be pressed before the computer accepts it as input; 4) *MouseKeys*: Option of using the numeric keypad on the keyboard to perform all mouse functions on the computer; 5) *SerialKeys*: Capability to perform all keyboard and mouse functions from an external assistive device (such as a communication aid) connected to the computer's serial port; and, 6) *ToggleKeys*: For individuals who cannot see toggle key status lights, this feature provides audible tones to indicate the status of the CapsLock, NumLock, and ScrollLock keys.

The ultimate goal of this program is to encourage the computer companies to take on the task of making their computers accessible. In some cases, the computer company has had its own programmers implement the accessibility features. In other cases, Trace Center has actually written the software or developed the hardware for transfer to the company.

Results—*Macintosh Environment*: The Trace Center has been working with Apple Computer over the past several years, assisting them in their efforts to implement access features. *StickyKeys*, *RepeatKeys*, and *MouseKeys* are now shipped as a standard part of every Macintosh and Apple IIGS sold.

Windows Environment: The Trace Center has developed a set of extensions to Windows—the six features have all been implemented for the latest version of Windows. There is also a "TimeOut" feature, allowing the Windows access features to automatically turn off after a certain length of time. The access package is currently available from Microsoft Corporation.

DOS Environment: *StickyKeys* and *RepeatKeys* have been available on a program called *One Finger*, developed and distributed by the Trace Center. The Trace Center also recently worked with IBM to develop a more complete package of access features for IBM computers using DOS. The package, known as *AccessDOS*, includes more keyboard features, and a "ShowSounds" feature for users with a hearing impairment. It is available free from IBM.

Recent Publications Resulting from This Research

Providing Computer Access Features Under DOS. Novak M et al., in Proceedings of the 14th Annual RESNA Conference, Kansas City, MO, 163-165, 1991.

[211] Trace Transparent Access Module (T-TAM) for Apple and IBM Computers

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Purpose—Certain people with physical disabilities cannot operate standard input devices for commercially available computers. Many of these individuals can, however, operate a special communication or computer access aid, using a control system such as an optical headpointer or single switch. This special aid in turn can be interfaced to the computer and used as an input device.

In the past, Keyboard Emulating Interfaces (KEIs) have been used to connect an aid to a computer. However, newer models of computers require the use of other standard input devices, in particular a "mouse" pointing device. Thus, the computer user must be able to use the mouse (or an equivalent) to operate the computer. This requires a General Input Device Emulating Interface (GIDEI), not just a KEI.

Progress—The goal of this development effort has been to create a commercially viable design for a GIDEI for Apple Macintosh, Apple IIGS and IBM PS/2 computers—all of which use a mouse as a

standard input device. This particular GIDEI has been named the Trace Transparent Access Module (T-TAM), since it provides "transparent" access to standard commercially available computer systems. The T-TAM development has been completed and it has been commercially transferred.

Methodology—The T-TAM is a hardware module that translates standard serial ASCII code output from a communication or computer access aid into the keyboard and mouse input signals required by the computer. Serial ASCII code was selected as the form of output from the aid, since it is by far the most common output interface on computer-independent aids.

Results—The device has been transferred to two companies for commercial production: Prentke Romich Company of Wooster, OH, and Words + Inc., of Lancaster, CA. Both companies are longstanding manufacturers of communication and computer access devices.

[212] Identification and Quantification of Cognitive Tasks in Computer Operation

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Sponsor: *National Institute on Disability and Rehabilitation Research; University of Wisconsin-Madison Graduate School*

Purpose—In order to understand the difficulties that persons with and without disabilities have in operating computers, researchers must understand the role of various task components involved in computer operation. This project is concerned with the ways in which different interfaces (input mechanisms) affect the difficulty of computer tasks. This is particularly important for persons with cognitive disabilities, for whom the interface may contribute additional procedural or memory load that inter-

feres with the ability to accomplish the computer task. We need information about what skills are involved at different stages of computer operation, and how different combinations of computer features affect performance in computer use.

Progress—A literature search has been performed and summaries compiled of the state-of-the-art knowledge on cognitive factors in computer use. Studies have been run, gathering data to explore the

relationship of interface performance to cognitive skills and abilities. Adult subjects have completed the full protocol. Data collection for normally developing children has been completed. Data collection has begun for subjects with cognitive disabilities and will continue through the end of 1991. Additional publications of results within and between subject groups will be prepared during 1991-92.

Methodology—This project is split into three study areas, each of which is addressed with the three designated subject groups: computer-experienced adults, normally developing children, and children with cognitive disabilities. The study areas include: 1) qualitative and quantitative comparison of subject performance with different interfaces; 2) relationship of different aspects of interface performance to cognitive skills of subjects; and, 3) analysis of sources of cognitive load for subjects both between tasks and during interface use (i.e., by subtasks within interface operation).

All of the studies in this section are within-subject designs. Subjects use five different interfaces

for computer operation: touchscreen, mouse, keyboard, locking trackballs, and nonlocking trackballs. Two computer tasks are compared: moving a visual object on the screen and sorting pictured objects into categories. Cognitive and perceptual-motor skills are sampled by several standardized and nonstandardized measures, as well as parent questionnaires.

Quantitative data collected include error rate, time for task completion, and time for each stage of interface operation. Qualitative experimenter scoring of performance reflects the completeness, accuracy, clarity, and promptness of responses. Additional information collected includes types of errors, learning patterns, and computer experience.

Recent Publications Resulting from This Research

Cognitive Skills Associated with the Operation of Various Computer Interfaces. Cress CJ, Tew JP, in Proceedings of the 13th Annual RESNA Conference, Washington, DC, 251-252, 1990.

Age-Related Differences in Interface Control in Normally Developing Children. Cress CJ, French GJ, Tew JP, in Proceedings of the 14th Annual RESNA Conference, Washington, DC, 257-258, 1991.

[213] Interface Training and Use by Persons with Cognitive Disabilities

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Sponsor: *National Institute on Disability and Rehabilitation Research; University of Wisconsin-Madison Graduate School*

Purpose—Because of the differences in learning styles and skills of persons with cognitive disabilities, we cannot assume that data from nondisabled subjects will necessarily predict or accurately describe performance in subjects with cognitive disabilities. Consequently, independent sampling of computer interface training needs to be conducted with persons with cognitive abilities who have levels of selected cognitive skills similar to the preschool children sampled in the previous study area. The results of this study will also contribute to theories of mental retardation by examining different patterns of learning across tasks, etiologies, and levels of mental retardation.

Progress—Subjects from the public schools (functional disability) and Down Syndrome Project

(Down syndrome) have been contacted, and data collection has begun.

Methodology—Children with mental retardation who score within the same mental age (MA) span for developing interface skills (2.5-5.0 MA) will complete the interface performance and training tasks described in the previous project reports. Children's learning styles, performance, and trainability for the different interfaces will be compared across different levels and types of cognitive skills and between disabled and nondisabled groups. Also, interface learning and skills will be compared between groups of children with mental retardation whose disability results from different causes: Down syndrome versus "functional" mental retardation. Results will be compared with assump-

tions in the literature that mental retardation has similar characteristics across etiology, and that the source of learning difficulties in mental retardation relates to specific difficulties in identifying and integrating important information about a learning experience.

Children were given two simple demonstrations of interface function and allowed the opportunity to intuit the operation of the interface from practice given this experience. If this was unsuccessful, the children were given increasing levels of cues (from explicit demonstration to graded manual contact) until they could successfully operate the control. If children could not decrease their level of cueing within the task restrictions, the more complex movement and sorting tasks were not given. Perfor-

mance and error patterns were assessed both over time (by task) and between children (by cognitive skill).

In addition, the children with mental retardation will receive a more detailed level of training cues aimed at promoting self-directed monitoring of the child's performance. Also, the research design will be a partial repeated measures, with each child completing performance and training evaluations with a random selection of 3 of the 5 interfaces. Forty children will complete the study (20 from each etiology group), resulting in 24 complete samples of behavior for the five interfaces.

Future Plans—Data analysis, reporting, publication, and presentation will occur during 1992.

[214] Computer Accessibility Design Manual

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—In order to assure that computers are more accessible to users with disabilities as they are sold "off the shelf," the Trace Center has worked with an industry-government alliance to develop a set of suggested guidelines for accessibility of computers and operating systems.

Progress/Methodology—Extensive work has been done by the Trace Center working with others in this field. A "White Paper," a "Design Guidelines" document, and an overview of design considerations have all been prepared and are currently being used by the computer industry. A chapter has been prepared for the *Handbook on Human-Computer Interaction* (Martin Hellander, Ed. [in press]), by invitation.

The existing design guidelines have been designed using a U.S. mail-based Open Task Force approach. The Task Force is "open" in that anyone can join the group—including consumers, designers, computer manufacturers, researchers, and rehabilitation equipment manufacturers. Membership in the group is defined as those individuals who remain active. All communication is conducted by mail:

electronic versions are available (formatted for the major computer brands), to accommodate people with disabilities who cannot read or handle paper. The Task Force approach has meant that individuals from different companies, geographic locations, or with different disabilities can all access and participate on an equal footing. This procedure has worked very well to date, and has resulted in the materials discussed previously. Because information can also be sent in anonymously or in confidence, it has also allowed manufacturers and specific individuals from corporations to freely express their concerns, without adverse reaction from others toward that particular company. Development and review of content and format of the design manual is being carried out in this same fashion.

Results—Version 4.2 of the manual is currently being disseminated to the field for review. It has been adopted and adapted by two major computer companies and was used in the final preparation of the GSA's guidelines. Version 5.0, which will include cognitive disabilities for the first time, is in progress.

[215] Guidelines for the Design of Consumer Electronic Products**Gregg C. Vanderheiden, PhD; Katherine Vanderheiden, MS; Christine Thompson, BS**

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Sponsor: National Institute on Disability and Rehabilitation Research

Purpose—Different types of impairment can lead to restrictions in the use of consumer electronic products or even render them unusable by people with disabilities. As with computers, there are simple design modifications that can be made in order to accommodate the needs of disabled people, without substantially adding to the cost of production or inconveniencing nondisabled people.

Progress/Methodology—A preliminary compilation of guidelines for the design of consumer electronic products has been completed and sent out for review and comment. The purpose of this project is to create a set of guidelines to be used voluntarily by designers and manufacturers. These guidelines discuss the full range of needs of persons with physical, sensory, and cognitive disabilities and discuss possible solutions. Not all solutions suggested are low-cost or no-cost, but these are suggested where feasible. The usefulness of certain modifications to nondisabled consumers are stressed—such as location and ease of use for controls.

The guidelines are treated as a working document,

sent out to consumers, researchers, and manufacturers for comment. These comments, along with additional material developed at the Trace Center, will be added to future editions of the document.

Results—A preliminary compilation of the guidelines has been completed. The first complete draft version of the document was completed and sent out for review in the fall of 1991. A task force was formed, similar to that developed for the design considerations for computers. The initial members of the task force included those individuals who contributed to computer design considerations, as well as individuals who expressed an interest. Other individuals and organizations will be able to join simply by expressing an interest and contributing ideas. The first full draft of the guidelines was forwarded to the task force for review in the fall of 1991, in cooperation with the Assistive Devices Division of the Electronic Industries Foundation and the Consumer Products Technical Group of the Human Factors Society.

[216] Campus/Library Information Systems Accessibility Manual**Jane R. Berliss, AMLS; Peter A. Borden, MA; Gregg C. Vanderheiden, PhD**

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Sponsor: National Institute on Disability and Rehabilitation Research

Purpose—Disabled (and able-bodied) individuals encounter computers and information systems in three main environments: daily living, employment, and education. In the education environment, there have been many computer access initiatives aimed at elementary and secondary special education students, both in and out of mainstream classes. By comparison, however, little has been done in post-secondary education (colleges and universities) and adult education (schools and public libraries) to assure that disabled people can access computers

and information systems. The gap will continue to widen as electronic information systems are used more and more extensively on campuses and in libraries. There is a general willingness to provide computer access, but that lack of knowledge and lack of resources have been the major obstacles. Information programs can provide a groundwork for acquiring the knowledge necessary to implement computer access. In addition, information can be provided on how to maximally exploit available resources, allowing and encouraging libraries and

campuses to pursue more aggressive computer access programs.

Progress/Methodology—A set of checklists with additional information has been created and is being distributed. A number of steps are being taken to create and disseminate information materials to libraries and campuses. Initial efforts have been targeted at university campuses, since these provide an opportunity to examine obstacles in both computer labs and libraries.

A document titled, "Checklists for Implementing Accessibility in Computer Laboratories at Colleges and Universities," has been developed. This document covers generic implementations of equipment—with steps delineated by time and money required to carry them out—and also procedures for assisting individuals who require more specialized equipment. An actual checklist form is provided on which staff can mark steps as they are implemented. The document provides a thorough explanation of the steps involved, along with lists of additional resources to consult.

The purposes of the checklists are to: 1) make it easier for administrators to plan and coordinate

computer access efforts and to set priorities; 2) provide a source of information and a common ground for planning for computing centers and disabled student services offices; and, 3) provide a comprehensive reference for computer access needs and strategies. Other steps in the process of creating effective information materials include pilot evaluations of computer access programs at several universities and presentations to appropriate audiences at conferences.

Results—The Checklist document was completed in draft form and distributed for comment—including distribution at national conferences related to computers and services for students with disabilities. Revisions have been made, and a publication version of the checklists is now available. IBM's National Support Center for Persons with Disabilities is also distributing the document.

Recent Publications Resulting from This Research

Checklists for Implementing Accessibility in Computer Labs at Colleges and Universities. Berliss JR. Madison, WI: Trace Research and Development Center, University of Wisconsin, 1990.

[217] General Input Device Emulating Interface (GIDEI) Standard

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—Certain people with physical disabilities cannot operate standard input devices for commercially available computers. Many of these individuals can, however, operate a special communication or computer access aid, using a control system such as an optical headpointer or a single switch. The aid in turn can be interfaced to the computer and used as an input device.

In the past, Keyboard Emulating Interfaces (KEIs) have been used to connect an aid to a computer. However, newer models of computers and software require the use of other standard input devices, particularly the "mouse" type of pointing device. Thus, the computer user must now be able to use the mouse in addition to the keyboard, to operate the computer.

In order that KEIs can be standardized across almost all communication and computer access aids, the Trace Center has developed and supported a KEI Standard. This was done to insure better compatibility among devices built by different manufacturers, thereby increasing the number of suitable options a user can choose from. Similarly, to address the need for standard emulating interfaces for other input devices than just the keyboard, such as the mouse, the Trace Center has begun development of a General Input Device Emulating Interface (GIDEI) standard.

Progress/Methodology—A standard has been developed and is in use. The GIDEI Standard is a document containing specifications for communicat-

ing desired actions to be performed with the standard keyboard and mouse. Communication and computer access aid manufacturers whose devices do not directly emulate input devices as a built-in feature are encouraged to design their devices with the capability to use the standard. Manufacturers who create general-purpose emulating interfaces are also encouraged to support the GIDEI communication protocol.

Results—Version 1, Revision 3 of the GIDEI Standard is completed. A hardware device designed at the Trace Center—the Trace Transparent Access Module (T-TAM) for Apple IIGS, Apple Macintosh

and IBM PS/2 and PC AT computers—has been programmed to operate according to the standard, and is now on the market. The GIDEI is also a part of the keyboard/mouse adaptations the Trace Center has developed for the Windows 3.0 operating system. Keyboard and mouse-emulating features are included in the Windows adaptations as part of a feature called “SerialKeys.”

A software KEI for MS-DOS computers developed by the Trace Center will be updated to support the GIDEI standard. The GIDEI specifications are available to manufacturers, and made available to other interested parties through the Trace Center Reprint Service.

[218] Simple Electrical Transducer (SET) Standard

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—The Trace Center first became involved in the standardization area in order to deal with the problems surrounding user interfaces to communication, control, and computer access aids. At the time, there were approximately 65 specialized interfaces commercially available. Unfortunately, no two manufacturers, even by accident, chose the same connectors or connector pin assignments for their controls. As a result, clinicians were restricted to the use of only a small number of these interfaces, since they were not interchangeable across aids without rewiring either the interface or the aid.

The Trace Center initiated an effort and, working with manufacturers and researchers from North America, Europe, and Japan, developed a Simple Electrical Transducer Interconnection Standard (SET Standard). The original SET efforts led to the adoption of a voluntary standard (SET Version 0.2). Since its introduction, about 80% to 90% of controls and devices addressed by the SET have conformed to most or all of the specifications. During 1987-88, a revision of the first standard was issued (SET Version 1.0), taking into account the suggestions and comments received from the field.

Progress/Methodology—A final version of the SET is completed and in use. The SET Standard seeks to standardize: 1) the physical connections between user controls and electrical/electronic aids; 2) the electrical specifications of the interfaces between controls and aids; and, 3) the categorization and labeling of controls and aids as to their electrical makeup.

The standard has been circulated as a working paper among interested parties. The document is distributed through the Trace Center Reprint Service. The document lays out all aspects of the standard as simply as possible while still remaining accurate. Appendices provide a quick reference to pin assignments for connectors.

Results—A final version of the SET is completed and in use. The Trace Center distributes the standard through its Reprint Service, and answers questions from manufacturers regarding compliance with the standard. The Trace Center will continue to support other organizations in their adoption of the SET standard. Future revisions or expansions of the standard may also be undertaken.

[219] Computer Writing System for a 20-Year-Old Woman with a Traumatic Brain Injury

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Sponsor: Neurodevelopmental Clinical Research Unit, Faculty of Health Sciences, Chedoke-McMaster Hospitals, Hamilton, Ontario

Purpose—Recent technological developments have been able to meet the varying physical needs of individuals requiring access to computers, both in hardware and software adaptations. However, providing mere physical access to a technical writing system is not an automatic assurance that the individual will become an efficient writer. One factor that determines efficiency is the rate at which messages are transmitted between an augmentative and alternative communication system user and his or her communication partner. Rate is an important concept for user satisfaction in written communication systems. Regardless of the mode of communication, the rate of interaction is varied according to the individual's physical, cognitive, perceptual, social, and linguistic skills. This project focused on rate as it relates to written augmentative communication systems.

The purpose of this study was to determine the most effective rate enhancement technique (from the two treatment possibilities of abbreviation-expansion and word prediction completion) for a written augmentative communication system for a 20-year-old woman with a traumatic brain injury. This young woman has no functional speech and is severely physically disabled as a result of an automobile accident.

Methodology—This case study utilized an alternating treatment design. The variables time of day and experimenters were counterbalanced across training sessions to rule out the influence of these extraneous variables. The subject participated in this project twice daily, for half an hour in the morning and half an hour in the afternoon three times per week. The treatments were alternated to prevent a pattern of treatment presentation.

Results—The results indicated that abbreviation expansion was more effective than word prediction completion in decreasing the subject's task completion time, and that this technique was better than straight typing. During the sixth session of the research project, the subject began to use codes for words that were not part of the original 17 words. She followed the same rule and generated *fd* for friend, *cm* for come and *wt* for write (this code produced the word *what*, so it was suggested that this was an exception and that *wr* was a better code). By the eighth session, the subject had added the codes *dd* for David, *hr* for hear, *fm* for from, *vt* for visit, *st* for sometime and *sn* for soon.

Word prediction completion appeared to require more time because the subject had to stop and look at the screen to retrieve the code that she wanted. Although these prediction codes did not change, the subject was not able to memorize the letter and corresponding number as quickly as the rule-based letter codes, so she continued to rely on the screen for her prompts.

Future Plans—Further research into the effects of rate enhancement techniques for individuals with disabilities is required to address the following areas: 1) How does a specific disability (i.e., acquired, congenital, degenerative) impact the selection of a rate-enhancement technique? 2) What are the cognitive and physical demands of rate enhancement and how can these be diminished by available rate-enhancement techniques? 3) How can rate enhancement techniques effect communication partners and the interaction process? and, 4) How can case study results be disseminated and used by manufacturers to improve rate enhancement software?

[220] LRW: The Long Range Wand for Windows 3.0

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Sponsor: Ontario Ministry of Universities and Colleges, University Research Incentive Fund; IBM Canada Ltd.; IBM Corporation

Purpose—The goal of this project is to develop an updated version of the Long Range Optical Pointer, originally developed at the TRACE Research and Development Center in Madison, WI. The new headpointing computer-access device should function with a wide array of IBM display options and with graphical user interfaces (GUIs) such as Microsoft Windows 3.0 and IBM OS/2 Presentation Manager.

Progress/Methodology—A prototype device, the Long Range Wand (LRW) has been designed and developed in conjunction with Design Technologies, Inc. (El Cajon, CA). The LRW acts as a mouse replacement for IBM PS/2 microcomputers running Microsoft Windows 3.0. It provides alternative keyboard access to the computer when used in combination with WiViK, an on-screen visual keyboard.

The LRW is an absolute pointing device compared to the mouse, which is relative. That is, the cursor always moves directly along the line-of-sight of the LRW. This is felt to be an advantage since the head cannot be picked up and repositioned as a mouse can with the hand. The user types by pointing and clicking at the keys, whose codes are then sent directly to the application. The user also uses the LRW to work within the application to select menu commands, tool palettes, scroll bars, and to highlight text. A standard mouse may be connected and will work simultaneously with the LRW.

The LRW extends the capability of the Long Range Optical Pointer (LROP) by providing access to higher resolution displays. A unique feature of the LRW is the use of head gestures and dwell times to perform button actions. This enables a user to utilize head movement alone for both pointing, selecting, and dragging operations. A short dwell time selects a cursor position; a downward nod performs a single-click; an upward nod performs a double-click; shaking to the right clicks the right button; and continued dwelling initiates dragging, which is completed by dwelling again. Dwell times

and the gesture actions may be adjusted to individual preferences. Filtering may also be applied to smooth the movement of the cursor.

Feedback is provided to the user to minimize errors. For example, when the cursor is pointing at a key on WiViK, its shape changes to a hand with a pointing finger. While a key is being selected, it is highlighted. When the selection is completed, an audible keyclick is heard. When using the switchless selection techniques, feedback is used to indicate that a selection is about to be made. The cursor is "locked" in position and a soft click is emitted. The appropriate gesture can then be performed. When the user is dragging, a scratching sound is produced.

Preliminary Results—Ten prototypes have been produced for field trials, which will be conducted in 1991 at sites across the United States and Canada. The results of these field trials will be considered in the next generation of the LRW. Appropriate software has been developed to enable the LRW to function within Windows 3.0. The LRW is currently the only headpointing device that can provide total access to a Windows 3.0 application without external switches.

Future Plans—Future development is planned to make the LRW function under IBM OS/2. Designs are also under consideration to make the LRW wireless.

Recent Publications Resulting from This Research

Nod at Your Computer: Switchless Selection Techniques Using a Headpointing Device. Hamann G et al., in Proceedings of the Annual Conference of the IEEE Engineering in Medicine and Biology Society, Washington, DC, 2296-2297, 1990.

Two Switchless Selection Techniques Using a Headpointing Device for Graphical User Interfaces. Hamann G, in Proceedings of the 13th Annual RESNA Conference, Washington, DC, 439-440, 1990.

Access to MS Windows 3.0 with the Long Range Wand. Hamann G et al., in Proceedings of the CSUN '91 Technology and Persons with Disabilities Annual Conference, 1991.

WiViK: A Visual Keyboard for Windows 3.0. Shein F et al., in Proceedings of the 14th Annual RESNA Conference, Kansas City, MO, 160-162, 1991.

[221] WiViK: A Visual Keyboard for Windows 3.0

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Sponsor: Ontario Ministry of Universities and Colleges, University Research Incentive Fund; IBM Canada Ltd.; IBM Corporation

Purpose—The goal of this project is to develop software to enable users to transparently enter text into any computer application within a graphical user interface (Windows 3.0) through any pointing device.

Progress/Methodology—People with physical disabilities may find graphical user interfaces (GUIs), such as Microsoft Windows 3.0, a tremendous barrier in accessing a computer. Most of the problems relate to the physical demands of the pointing device, which involve moving with relatively fine continuous control, clicking one or more buttons, dragging while holding the button, and moving between the keyboard and pointing device.

The development of a visual keyboard within Windows 3.0 presents unique problems: achieving functional text-entry and supporting manipulation of GUI objects (e.g., windows, icons, menus, scroll bars, text blocks). Only the first problem is of concern to users who have pointing ability. They can manipulate objects with some pointing device and only need support to enter text. Here, the point and click ease-of-use of GUIs is an advantage. Users who have only limited pointing or clicking ability, or who may utilize an indirect scanning technique, are at an extreme disadvantage. Manipulation of objects may be very difficult or impossible. It is suggested that a visual keyboard alone cannot solve this problem.

Software has been developed, called WiViK (Windows Visual Keyboard), that displays an on-screen keyboard and enables the user to transparently access any Windows 3.0 application with various pointing devices, including mice, trackballs, joysticks, touchscreens, and headpointers. No modifications to the applications are necessary. Full compatibility with standard IBM keyboards is provided along with the addition of several features to make its use easier with pointing devices.

When a key is selected within WiViK, key-strokes equivalent to a standard physical keyboard are entered into the currently active application. The standard keyboard remains functional throughout all operations. The WiViK keyboard is displayed within a movable, resizable window. The number and arrangement of keys, key widths, key labels, key label font, and key spacing can be changed by the user. Keys are automatically resized when the keyboard is resized.

Multiple WiViK keyboards, each with a different key layout, may be displayed and used simultaneously. For example, the user may choose to have a basic keyboard on-screen at all times and load in special-purpose macro keyboards when required (such as a numeric keypad). This reduces the number of keys that need to be displayed in any one keyboard. When a pointing device is used, all of the graphical user interface features of Windows are accessible, although some actions may still be difficult. Scanning is specifically not yet implemented because many problems are unresolved in supporting non-keyboard actions.

Future Plans—Clinical research will be conducted with WiViK to determine strategies for providing access to graphical user interfaces with WiViK for individuals with poor motor control. This will include scanning access and a quadrant pointing technique. This latter approach allows the user to roughly point to and select a quadrant of the keyboard. That quadrant will expand to the full keyboard window and the user can point and select another quadrant which expands again. The next quadrant selection will select a key.

Recent Publications Resulting from This Research

WiViK: A Visual Keyboard for Windows 3.0. Shein F et al., in Proceedings of the 14th Annual RESNA Conference, Kansas City, MO, 160-162, 1991.

[222] Development of a Communication Aid for Severely Spastic Users**Jan Goezinne; Ton van Lunteren; Henk G. Stassen**

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Sponsor: Phelps Foundation

Purpose—The purpose of the project is to design a communication aid for severely spastic users in which optimal use is made of remaining motor functions, thereby increasing the speed of communication in comparison with the presently available devices.

Methodology—Present communication devices for spastic users are often based on enlarged keyboards to enable selection of the desired character. For severely spastic users, however, there is only the alternative of sequential selection in a matrix by one or two input devices with an on/off character. The present project aims at an input device that enables a selection from more than two classes at a time. It makes use of a two-dimensional displacement sensor such as a mouse or a trackball in combination with a filter and selector that can be adjusted to the capabilities of the individual user.

Progress—An experimental setup has been built with commercially available components. The signals corresponding with the horizontal and vertical displacements of the hand were low-pass filtered before being presented on a screen.

A number of experiments were conducted with spastic children who were asked to follow a jumping symbol with a hand-controlled cursor based on the output of the adjustable filter. It was found that the high-frequency spastic component could be greatly reduced, thereby increasing the output of the children in terms of possible speed of communication.

Future Plans/Implications—Present activities aim at the development of a number of special sensors and a corresponding interface for a PC that contains an adjustable filter. In addition, the possibilities will be investigated of the application of adaptive filter theory to enable easier individual adjustments.

[223] Development of a Voice Output Intelligent Communication Enhancement System (VOICES) for Nonspeaking Individuals**Peter A. Reich, PhD; Penny Parnes, BSc, DSPA**

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Sponsor: Social Sciences and Humanities Research Council of Canada

Purpose—The purpose of this project is to design a communication aid which can use linguistic and semantic information to make intelligent guesses as to what the communicator intends to say, thus reducing the number of button pushes necessary to produce grammatically correct speech.

Methodology—This project proposes a system (rather than a particular device) for creating communication aids tailored to each individual user. The main component of such a system is an inventory of about 3,000 symbols, each equipped with vocabulary items and their associated grammar. The user,

and people working with the user, will be given tools from the inventory provided that will make it easy to construct and modify the device to suit the user.

The system will be programmed on Macintosh computers in SuperCard, an advanced programming environment similar to but more powerful than Hypercard. Portable computers will be used that can run on batteries and be mounted on wheelchairs. The symbols that will be used are Blissymbols, which are efficiently stored, displayed, and printed on Macintosh computers by means of the Bliss Template Font, a font developed by the principal investigator.

Future Plans—The first year of the project will be focused on creating the system, and the second year

on testing with users, evaluating its use, and making modifications in light of what is learned.

[224] Modeling of Performance with Computer Access and Alternative Communication Systems

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Sponsor: *University of Michigan Rehabilitation Engineering Program; University of Michigan Rackham School of Graduate Studies*

Purpose—This project explores the application of engineering modeling techniques to improve understanding of the user interface of augmentative communication and computer access (AAC) systems. There are two prongs to this work. The first is empirical, involving the observation of behavior and measurement of performance during use of an AAC system. The second is analytical, involving the development and refinement of quantitative models that accurately represent these observations. The goal of the modeling process is to provide both developers and clinicians with a framework that can improve the design and delivery of AAC systems. If we are successful, the models will be able to quantitatively predict user performance with these systems and simulate the effects of varying user and system characteristics. The modeling process also offers a valuable qualitative analysis, since it provides the opportunity to carefully analyze the interaction between the user and an AAC system, under a wide range of conditions.

Progress/Methodology—The “GOMS” family of modeling techniques has been appropriated for use in this project from the field of human-computer interaction, where it has been used with some success. The model provides a comprehensive description of user performance based on system-specific parameters as well as the cognitive, perceptual, and motor capabilities of the user. While GOMS techniques can be used to model any type of interactive computer system, our current focus is on letter-based row-column scanning interfaces. Separate models have been developed to represent two general types of scanning systems, one with word prediction and one without.

Model validation studies are underway that will compare the performance predictions made by the models with the actual performance of subjects. The

protocol for the study has been designed, and development of the necessary software tools has been completed. These tools include: 1) a configurable letter-based scanning system, to allow simulation of numerous existing scanning and word prediction techniques; 2) a stand-alone data collection utility that records the time and content of all selections made by the subject during use of the system; and, 3) a statistics utility that generates a profile of the subject's performance using the raw data from the data collection utility.

Preliminary Results—Model simulation results to date suggest the possibility that word prediction interfaces, developed as a faster alternative to row-column letter scanning, may actually be less efficient than letter scanning in some situations. Preliminary model validation results have been gathered for letters-only scanning, both in the laboratory and in a clinical case study. The model performance predictions compare quite closely to actual performance data, over a wide range of scanning timing parameters, providing support for the quantitative accuracy of the modeling technique.

Future Plans—A primary goal is to complete the data collection phase of the model validation studies. The empirical data will be analyzed to provide estimates of the learning rate and long-term text entry speed attainable when using letter-based scanning with and without word prediction. The data will then be compared with model predictions to determine their accuracy under a variety of conditions.

Recent Publications Resulting from This Research

The Effectiveness of Word Prediction. Horstmann HM, Levine SP, in Proceedings of 14th Annual RESNA Conference, Kansas City, MO, 100-102, 1991.

D. Private and Public Programs

[225] Proposal for a Survey of Attendant Care Arrangements for Indigent Spinal Cord Injured Persons in Louisiana

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Sponsor: American Association of Spinal Cord Injury Psychologists and Social Workers

Purpose/Methodology—Spinal cord injuries resulting in quadriplegia above the C7 level do not allow individuals to return to fully independent living in the majority of cases. Thus, some level of attendant care is required for most higher level quadriplegics. For patients with financial resources, health insurance coverage, insurance settlements, or strong family support, attendant care is usually not a problem. However, for the indigent spinal-cord-injured person with no financial resources and a weak or nonexistent family support system, attendant care can be a serious problem. In some cases, individuals who otherwise would be able to return to their communities with limited attendant care require nursing home placement. In other cases, individuals may return home with inadequate assistance, resulting in preventable medical and social

problems. This study will investigate the attendant care arrangements of indigent higher level quadriplegic patients, with measurement of such variables as attendant care training, general educational level, relationship, availability, reliability, time in the home, and services provided. A representative sampling of the caretakers of C7 and higher level quadriplegics followed in the spinal cord injury clinic of the Louisiana Rehabilitation Institute will be surveyed and the results collated, analyzed, and reported. Planned further studies will correlate the findings of this study with the incidence of medical and social problems in this population and will attempt to remediate identified problems with attendant procurement, training, and other interventions suggested by the findings of the proposed study.

[226] National Information System on Technical Aids

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Sponsor: Italian Ministry of Health

Purpose—The goal of this project was to provide the Italian National Health Service with a computerized information system supporting the choice of technical aids for rehabilitation and independent living.

Methodology—Over the past years, a computerized information system has been developed concerning technical aids. It has been operational since 1982 through remote access and since 1988 through periodic distribution of floppy disks to be loaded onto personal computers. For the current project, a careful analysis was performed concerning the:

- effectiveness of such a system in the context of rehabilitation services
- educational needs of rehabilitation professionals
- organizational requirements of the National Health Service
- legislative/administrative context.

This analysis led to the:

- adaptation of the information system for nationwide distribution
- provision of an educational curriculum to rehabilitation professionals using the information system

- definition of a model for a local (first-level) technical aid information center supported by the information system
- definition of a model for a regional (second-level) technical aid information center supporting all local centers within its area.

The local and regional models have been tested and are ready for future nationwide distribution to 20 regions and 755 local health authorities.

Results—The computerized information system now contains extensive information on 4,500 technical aids available on the Italian market; 2,500 manufacturers and suppliers; 2,500 noncommercial organiza-

tions; disability legislation, and selected literature. It is also prepared for managing pictures and test reports of technical aids. A facility has also been provided for recording and retrieving local information on the clients of a technical aids information center. Distribution is ensured through periodic mailing (3 times a year) of sets of compact disks (CD-ROM). Two regional centers other than SIVA (which is located in Northern Italy) have been established, in Rome (central Italy) and in Naples (southern Italy).

Future Plans—An operational plan has been submitted to the Ministry for nationwide implementation of the model.

[227] Operational Definition of Independence

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—This project is designed to develop an operational definition of independence that incorporates four components of the term: perceptions of control over one's life, psychological self-reliance, physical functioning, and behavioral and environmental resources. The objective is to develop an assessment instrument to quantify an individual's independence in each of the above domains.

Progress/Methodology—After extensive search of the literature and expert consultation, the Personal Independence Profile (PIP) was constructed to operationalize the consensus definition. The PIP consists of three subscales: Part I—Control: 10 items selected from Flanagan's Quality of Life Domains; Part II—Psychological Self-Reliance: 34 items from Fordyce's Independence Scale that deal with psychological factors such as competitiveness, self-esteem, and group autonomy; and Part III—Physical Functioning: 5 sections from the Arthritis Impact Measurement Scale (AIMS), a Guttman-type ordering of general functional ability items. A fourth section of the PIP comprises 22 demographic, behavioral, and environmental questions.

The next step in the development of the PIP was to conduct various tests of its validity. Two

hundred subjects in 10 independent living centers across the country were sent the PIP, 120 of whom also completed questionnaires designed to measure the same or similar constructs to test the convergent validity of the PIP. A sample of 185 of these 200 subjects produced data that were complete enough to enable cluster analysis of the PIP-Control, PIP-Psychological Self-Reliance, and PIP-Physical Functioning scores.

Results—Testing of the reliability of the PIP resulted in Cronbach alpha coefficients of 0.86 for control, 0.79 for psychological self-reliance, and 0.93 for physical functioning. The internal validity of all three constructs of the PIP was supported by high correlations with other scales designed to measure similar constructs and low correlations with scales that do not measure similar components of independence.

Cluster analysis of the three PIP scales from 185 subjects using Ward's minimum variance procedure yielded three salient profiles: 1) independently minded and less disabled; 2) independently minded and more disabled; and, 3) nonindependently minded. The 81 Profile A participants had high standardized mean scores on all three subscales.

Compared to the other two profile groups, this group reported the highest level of perceived independence, tended to feel in control of the things that were important to them, used the fewest prescription drugs, spent the fewest days in the hospital in the past 6 months, and had the highest productivity. The Profile B cluster contained 49 participants who had high scores on psychological self-reliance and control, but low scores on physical functioning. Though similar to Profile A, they differed markedly in their much higher degree of physical impairment. This group had the highest level of perceived health, used the most prescription drugs, made few trips to the hospital emergency room, spent the most days in the hospital, and made the fewest visits to the doctor's office. As in the Profile A cluster, these participants were highly productive. Profile C differed markedly from the other two clusters. The 55

participants in the Profile C cluster had low scores on the psychological self-reliance and control subscales, but highly variable scores on the physical functioning subscale. Of the three profile groups, this group reported the lowest level of perceived independence, the lowest level of perceived health, the most frequent visits to hospital emergency rooms, a high number of days in the hospital, and the most visits to the doctor. They were the least productive of all three groups.

Future Plans—Using the same 200 participants, a study is underway to examine possible predictive correlates of perceived control, such as educational attainment, productivity, perceived health status, living arrangements, mobility, and environmental accessibility.

[228] Evolution of Independent Living Programs: A Longitudinal Study

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—The purpose of this project is to maintain a database on the status of independent living programs (ILPs) nationally, and to identify trends in the development of ILPs, the emergence of issues encountered in the delivery of independent living services, and changes in the characteristics of consumers of these services.

Progress—Profiles of each program responding to a full-length survey have been published in the *ILRU Registry of ILPs*. In late 1988, a revised and updated survey instrument was mailed to over 400 programs listed in the *ILRU Directory of Independent Living Programs*. Information was solicited concerning populations served, services provided, characteristics of persons providing services, methods by which services are provided and programs administered, sources of funding, and relationships between programs and their communities. Responses from 189 programs were received and analyzed. Beginning in 1991, programs included in the *Directory* will be restricted to those that receive

funds under Title VII, Parts A, B, and C of the amended Rehabilitation Act of 1978, or those that qualify to be considered an independent living center by meeting the four minimum criteria for consumer involvement and diversity of independent living services specified in those amendments and operationalized by ILRU.

Results—A comparison of the 1986 and 1988 results has revealed some promising trends. Significant improvements have been made in both the volume and quality of service delivery; board and staff training; proportions of boards, executive directors, and staff with disabilities; and the size of federal grants. In 1988, more than three-fourths of the programs offered training to the board, and 94.7% offered training to the staff. By contrast, only 6% of the programs reported offering board training and 11% staff training in 1986. People with disabilities now occupy a majority of executive director, administrative, and staff positions, compared to filling less than half of these positions in 1986. In

1986, only 51% of programs receiving Title VII funds complied with National Council on Disability (NCD) standards for the involvement of persons with disabilities in direction, management, and service delivery. Compliance had risen to 82.6% by 1988, and unlike the 1986 findings, there was a significant relationship ($p < 0.05$) between compliance and both the receipt of funds and the amount of funding received. Complying programs offered significantly more services and served significantly more persons than did noncomplying programs. These findings have strong implications for federal policy and funding in the independent living area.

Additional analyses were done to determine the impact of program age, consumer control, and budget size on the operation of ILPs. Results reflected the wide diversity of program characteristics. Older programs tended to have more diverse funding. Programs with higher levels of consumer control tended to have more staff with disabilities, engaged in more advocacy activities, and participated more in networks. Programs with larger

budgets were more likely to offer residential housing services and were less active in advocacy and awareness activities.

Future Plans—The *Directory of Independent Living Programs* is updated and reissued approximately five times per year. Research staff will continue to update the *Directory* and respond to specific inquiries with individualized data runs and reports. Analysis will continue on the ILRU National Database on Independent Living Programs, with trends published as they emerge.

Recent Publications Resulting from This Research

Independent Living Programs: The Impact of Program Age, Consumer Control, and Budget on Program Operation. Nosek MA, Roth PL, Zhu Y, J Rehabil 56(4):28-35, 1990.
Evolution of Independent Living Programs. Nosek MA, Zhu Y, Howland CA, Rehabil Counsel Bull (in press).
Relationships Between Compliance with Federal Standards for Independent Living Centers and Diversity and Amount of Funding. Nosek MA, Zhu Y, Howland CA, Rehabil Counsel Bull (in press).

[229] The Definition of "Peer": Consumer Perspectives and Significance in the Delivery of Counseling Services

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Sponsor: National Institute on Disability and Rehabilitation Research

Purpose—This project is intended to assess the perceptions of persons with disabilities regarding the definition of peer and the provision of counseling services by peers. Peer counseling is essential to consumer involvement in independent living programs, as evidenced by the mandatory inclusion of peer counseling in all independent living programs receiving funding under Title VII of the 1978 Amendments.

Progress—The quasi-experimental design of this project focused on perceptions of counselor credibility. The research question asked which factors account for the greater variance in ratings of counselor credibility: disability status of the counselor, whether or not the counselor was professionally trained, or whether or not the content of the

interaction was disability-related. Seventy-two subjects completed selected items from the Counselor Effectiveness Rating Scale after viewing photos of four counselors, reading and hearing biosketches for each, and listening to tape recordings of two consumers describing a problem to a counselor.

Results—The data were analyzed using a double multivariate repeated measures analysis of variance within subjects factors (Professionalism, Disability, and Vignette content, each with two levels) and five dependent variables (Experience, Expertness, Interest, Understanding, and Ability). Although the three-way interaction among Professionalism, Disability, and Vignette content was not significant, all three multivariate two-way interactions were statistically significant. An important finding of the study

is that disability status of counselors significantly affects ratings of counselor credibility. For both professionals and nonprofessionals, disabled counselors received higher mean ratings than did nondisabled counselors on all five measures, although this difference was smaller for professionals. Also, for the disability content interaction, subjects rated disabled counselors more favorably than

nondisabled counselors on all five measures.

Recent Publications Resulting from This Research

Perceived Counselor Credibility by Persons with Physical Disability: Influence of Counselor Disability Status, Professional Status, and the Counseling Content. Nosek MA, Fuhrer MJ, Hughes SO, *Rehabil Psychol* 36:153-161, 1991.

[230] Assisting Community-Based Rural Independent Living Programs

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—ILRU will identify community-based programs that are engaged in the delivery of independent living and supportive services to persons with disabilities who live in rural areas. Criteria will be established for exemplary operational practices, and programs will be selected that best meet these criteria. Materials will be solicited from exemplary programs for inclusion in ILRU's *Resource Materials Directory*. Six programs—two in isolated rural communities, two in moderately rural communities, and two in urban settings that engage in outreach to rural communities—will be selected as demonstration sites for receiving intensive supportive services by ILRU over the duration of the project. The outcome of these efforts will be assessed using a comprehensive approach to evaluation. The final goal is to make rural-focused technical assistance services and supportive materials available to all rural independent living programs.

Progress—An advisory committee has been established, composed of persons representing the Association of Programs in Rural Independent Living (APRIL), the National Council on Independent Living (NCIL), the Council of State Administrators

of Vocational Rehabilitation (CSAVR), researchers and practitioners in rural rehabilitation service delivery, and the Research and Training Center on Rural Rehabilitation Services. A Delphi questionnaire has been prepared and sent out to all independent living programs requesting the staff to list the five most pressing problems confronting providers of independent living services to rural areas. Next, a composite listing of these problems will be sent to these programs, asking that they rank the top 10 problems.

Results—A questionnaire sent to independent living programs in 1991 identified 300 programs that offer services to people with disabilities residing in rural areas. To date, approximately 40% of the Delphi questionnaires have been returned. Analysis of data is in progress.

Recent Publications Resulting from This Research

Independent Living Services for Children with Disabilities in Rural Areas. Smith QW et al., *Rural Spec Educ Q* (in press). The Role of Independent Living Centers in Delivering Rehabilitation Services to Rural Communities. Nosek MA, Howland CA, *Am Rehabil* (in press).

[231] Instrumental Social Support as a Buffer of Psychological Stress for Persons with Physical Disabilities

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—A primary purpose of this project is to understand some of the principal determinants of psychological stress in people with physical disabilities. This project is designed to test the hypothesis that instrumental social support—specifically, personal assistance with activities of daily living—is a key factor in determining the degree to which physically disabled people experience stress and psychological dysphoria. Also examined is whether the life satisfaction is related to severity of disability and satisfaction with social support provided by personal assistants.

Progress—Staff in eight centers for independent living in Federal Region VI recruited subjects for the study and distributed questionnaire packets. Upon receipt of completed surveys, the researchers interviewed subjects by telephone concerning their level of social support. Approximately 81% of subjects returned surveys and participated in telephone interviews. A sample of 45 respondents used personal assistance. Data analysis is complete, and a manuscript presenting the results is in progress.

Results—Self-appraised adequacy of personal assistance in terms of availability, quality, consumer control, and cost was found to be a significant factor in the life satisfaction of people with severe disabilities. Appraisal of personal assistance was not associated with whether assistance was obtained through a formal agency or whether it was provided on a paid or unpaid basis. Life satisfaction was positively related to social integration and occupation, two measures of handicap. Life satisfaction was not related significantly, however, to severity of physical disability. Whereas environmental or social limitations associated with disability had an adverse impact on life satisfaction, functional limitation had little impact. People who were mobile in their homes and communities and involved in occupational and avocational interests were generally satisfied with their lives. These findings suggest that satisfaction with personal assistance positively impacts life satisfaction, an effect that is relatively stable across disability levels.

[232] Development of an Instrument to Measure Adequacy of Personal Assistance Services

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—This series of studies is designed to develop and test an instrument for assessing the adequacy of various systems for delivering personal assistance services to persons with diverse severe physical disabilities, their satisfaction with these services, and the effects of personal assistance on employability and health.

Progress—Summaries of more than 150 publications related to personal assistance were compiled and published in 1988. Since then, a literature-based list of personal assistance program components and characteristics relevant to adequacy has been generated and validated by expert review and field testing. During the process of developing adequacy criteria

and indicators, it has been necessary to distinguish between assessment and adequacy from a consumer perspective versus a formal program review. Since methodologies for administrative evaluation of programs are abundant and consumer-focused adequacy criteria scarce, development proceeded from a consumer perspective. It was also necessary to identify distinctions between adequacy and consumer satisfaction and incorporate satisfaction criteria into the instrument. After finalization of criteria and categorization of items by topic, operationalized indicators were developed. The resulting working draft of the instrument—the Personal Assistance Satisfaction Index—has been used in several studies

to evaluate model personal assistance services and to assess the role of personal assistance in the health and employability of people with severe disabilities. Statistical analysis to determine the internal validity of indicators and factor analysis to test the validity of criteria categories have been performed. These results will be used to further refine the instrument. Tests of internal validity are also underway.

Results—Factor analysis of the adequacy criteria revealed two prominent factors, quality/control and availability/cost. Cronbach alpha of 0.91 established the reliability of 16 items.

[233] Arrangements for Receiving Personal Assistance Services

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Sponsor: National Institute on Disability and Rehabilitation Research

Purpose—This study is designed to identify the most common arrangements for receiving personal assistance services; to evaluate quality, control, availability, and cost in four different models of personal assistance programs; and to assess the satisfaction levels of persons with severe physical disabilities who obtain personal assistance through these program models. Relationships among living arrangement, who provides assistance, employment status, and productivity will be assessed. Recommendations will be made for making formal personal assistance more acceptable, affordable, and available to persons who rely on family assistance (79% of people with disability-related functional limitations), but who could be more productive with additional hired assistance.

Progress/Methodology—The Baylor College of Medicine Research and Training Center on Spinal Cord Injury and Independent Living Research Utilization (ILRU) have used a registry of 655 persons with spinal cord injury (SCI database) to assess relationships between living arrangement and provision of personal assistance by family, nonfamily, or a combination of both. This now comprises the control group for all subsequent studies of quality,

control, availability, and cost of personal assistance services.

Productivity will be assessed by using SCI data that correspond to five components of DeJong's Productivity Scale—work status, educational status, activities outside the home, activities inside the home, and homemaking activities. The resulting productivity score will be analyzed with living arrangement and who provides assistance in a two-way analysis of variance (ANOVA).

To assess relationships between satisfaction with personal assistance and age, duration of disability, living arrangement, income source, productivity, marital status, educational attainment, number of hours of assistance used, and who provides assistance, the above results will be combined with data from telephone interviews of 75 subjects from the SCI database who use more than 1 hour of assistance daily. These subjects have been selected using stratified random sampling procedures and are currently being interviewed. Twenty-five of the sample use family assistance only, 25 nonfamily only, and 25 a combination. Interviewers are trained consultants from the Houston community who use personal assistance themselves. The interview content consists of demographic information and the Personal Assistance Satisfaction Index.

Relationships between control and satisfaction are being evaluated in four different models of personal assistance delivery: 1) state rehabilitation agency provision; 2) independent living center provision; 3) progressive home health care agency provision; and, 4) consumer co-op provision. The Personal Assistance Satisfaction Index was mailed to 87 consumers who obtain personal assistance through these programs, and data were analyzed using one-way ANOVA and the Tukey multiple comparison test.

Preliminary Results—The preliminary study of 655 persons with spinal cord injuries revealed that of the 286 who used personal assistance, 77% lived with relatives. Of those, family provided assistance to 61%, nonfamily assisted 17%, and a combination of family and nonfamily assisted 22%. Of the 10% living with nonfamily, most (70%) received assistance from nonfamily, and of the 13% living alone, nearly everyone received assistance only from nonfamily. Disregarding living arrangement, only family assisted 50%, only nonfamily assisted 31%, and a combination assisted 19%. The reasons for the unexpectedly higher rate of paid assistance usage will be explored in subsequent studies comparing differences between persons with spinal cord injury

and those with other disabilities. One possible explanation is that persons with spinal cord injury may be more likely than persons with other types of disabilities to have access to private sources of funds, such as insurance settlements, and to have had formal rehabilitation that included training in managing assistance needs.

Preliminary results from the survey of use of four personal assistance models indicate that satisfaction levels were significantly higher ($p < 0.05$) for the 25 consumers who obtained services through a progressive home health care agency. This model enabled the greatest flexibility in consumer control; consumers in this highly satisfied group had the option of deciding the extent of the agency's involvement in arranging personal assistance services. Satisfaction levels with the home health care agency were significantly higher than satisfaction with the state provider and the consumer co-op models, but only slightly higher (nonsignificant) than the independent living center.

Recent Publications Resulting from This Research

Personal Assistance Services: A Review of Literature and Analysis of Policy Implications. Nosek MA, J Disabil Policy Stud, 1991.

[234] Effect of Personal Assistance Services on the Long-Term Health of a Rehabilitation Hospital Population: Perceptions of Rehabilitation Professionals

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—This study was designed to test the hypothesis that personal assistance with activities of daily living significantly affects the ability of persons with severe physical disabilities to maintain good physical health.

Progress/Methodology—A sample of 41 subjects recruited through the American Congress on Rehabilitation Medicine (ACRM) were interviewed by phone. Interviewees consist of 7 physicians, 10 nurses, 9 social workers, 8 physical therapists, and 7 occupational therapists from 5 medical rehabilitation centers. Frequency analysis was conducted on

all responses to questions, and techniques of qualitative analysis were used to code comments and establish a grounded theory. Based on the results, a manuscript has been submitted for publication about the effect of personal assistance on the long-term health of a rehabilitation hospital population.

Results—Results supported our hypothesis; rehabilitation professionals believe that inadequate personal assistance contributes to poor physical and mental health for individuals with severe physical disabilities and their families. The most commonly cited

health condition was skin breakdown, followed by urinary tract infections, pulmonary infections, and contractures. Inadequate personal assistance also led to extended hospital stays, threats to safety, poor nutrition, and poor personal hygiene. Nearly all those interviewed considered reliance on family alone for assistance to be inadequate; common effects of such reliance included burnout, family role changes, and economic strain.

The interviewees indicated that the more time consuming and sophisticated were the tasks needed, the more difficult it was to obtain sufficient assistance. Families were often unable to provide adequate assistance due to a preexisting struggle to survive, a dysfunctional family structure, or unwillingness to fill the role of assistant. Persons with the best health seemed to have a combination of family and nonfamily providing assistance. More than half of those interviewed observed the lack of agencies providing affordable, comprehensive home services. Also noted was the need for a pool of screened personal assistants available for respite and emergency backup. Quality of assistance was compromised by inadequate training, unreliability, and turnover of assistants, and by regulations limiting hours and tasks assistants are allowed to perform. Nearly half of the interviewees also mentioned lack

of financial resources as a major cause of inadequate personal assistance. In addition, regulations that require medical supervision of assistance with basic activities of daily living unnecessarily inflate fee scales and limit the options for receiving assistance from outside the family. When nonfamily assistance is available, persons with disabilities often lack the ability to locate, interview, hire, instruct, supervise, terminate, and otherwise manage personal assistants.

Solutions suggested for improving adequacy of personal assistance focused on establishing a comprehensive system for delivering services that could coordinate services from home health agencies, independent living centers, and rehabilitation hospitals. Most interviewees advocated reform of current insurance policies, including Medicare, to allow coverage of expenses for personal assistance services.

Future Plans—More sensitive measures of health status and extent of personal assistance needed must be developed. The effects of the inability to control the quantity and quality of personal assistance received by individuals who desire to take charge of their health also needs to be studied.

[235] Demonstrating a Model Approach to Independent Living Center-Based Assistive Technology Services

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—This project is designed to establish, operate, and evaluate the effectiveness of an independent living center-based assistive technology service. The main objective of this service is to provide appropriate, timely, and affordable repair of assistive equipment and devices; teach preventive maintenance practices to increase the longevity of assistive equipment and devices; refer consumers whose equipment is irreparable to appropriate service providers or vendors who can assist them in obtaining new equipment; and counsel consumers about sources of sponsorship for equipment repair

or the acquisition of new equipment. Assistive technology includes telecommunication devices for hearing-impaired persons, computerized communication boards for persons with aphasia, environmental control systems for persons with movement restriction, and microprocessor controls on wheelchairs.

Progress—Sixteen independent living centers that offer equipment repair services have been surveyed by telephone, and preliminary results are available.

Results—Only three centers reported actually repairing equipment; the remainder provide information and referral and financial assistance for repairs. Services are generally for-profit and include equipment sales, equipment loans while broken equipment is being replaced, preventive maintenance checks, and delivery of repair services by center-owned vans. Service technicians are salaried and trained by the equipment dealers. Most repairs are paid through Medicare, Medicaid, or private insurance.

All 16 centers provide information and referral. Consumers usually are referred to a medical supply shop, vendors who sell or install equipment, or a

self-employed mechanic in the community who is also willing to fix wheelchairs or other equipment. Typical problems encountered include obtaining reimbursement from Medicare for sophisticated technology used by persons with severe disabilities, making consumers aware of the latest technology available, selling enough equipment to qualify as a dealer of certain manufacturer's products, finding and keeping staff who are qualified to do repairs, long waiting periods for the return of broken equipment from the manufacturer, making the repair shop easily accessible, and meeting the delivery demands to rural homes that are located far from the shop and far from one another.

[236] Increasing the Ability of Independent Living Centers to Serve the Hispanic Population

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Sponsor: National Institute on Disability and Rehabilitation Research

Purpose—According to the Bureau of the Census (1980), Hispanic persons constitute 6.4% of the general population, yet only 1% of persons receiving independent living services are of Hispanic descent. This project is intended to obtain information on the best approaches for providing independent living services to this under-represented population and to provide centers around the country with service information and technical assistance to enable them to effectively serve Hispanic constituencies.

Progress/Future Plans—Ninety-three independent living centers (ILCs) have been identified as providing services to Hispanic consumers. Executive directors of 17 ILCs who report that at least 10% of their consumers are Hispanic have been surveyed by telephone about such topics as the amount and type

of services received by Hispanic consumers, their representation on boards of directors and center staff, informational materials targeted to the Hispanic population and provided in Spanish, differences in service provision compared with services to other consumer groups, and problems encountered in meeting the needs of this population.

Survey results are currently being analyzed, and will be presented in a workshop on improving service delivery for persons of Hispanic descent at the annual National Conference on Independent Living. Results of input from the workshop participants will be published in English and Spanish in both printed and audio versions. In addition, a "How-to" publication will be prepared to aid ILCs in serving Hispanic people.

[237] Collaboration Between Medical Rehabilitation Programs and Independent Living Centers in Facilitating Independent Living by Persons with Recently Incurred Spinal Cord Injury

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Sponsor: National Institute on Disability and Rehabilitation Research

Purpose—During the period immediately after discharge from a medical rehabilitation program, health maintenance and independent living skills taught during hospitalization must be put into practice, and adjustment problems must be resolved that could not be prepared for adequately during hospitalization. Yet knowledgeable assistance is difficult to obtain on a timely, affordable basis during the post-discharge period. Independent living centers can provide vital services in facilitating transition of the individual with a recently incurred spinal cord injury from hospital-based rehabilitation to an independent, productive life in the community. Differences in program philosophy and style of service delivery, however, may make it difficult for medical rehabilitation programs and independent living services to work together effectively. This project is designed to develop, implement, and systematically evaluate a cooperative reentry program involving a medical rehabilitation program and an independent living center for facilitating the post-hospitalization life adjustment of persons with recently incurred spinal cord injury.

Progress/Methodology—In a longitudinal cycled treatment and comparison group design, 50 eligible

inpatients with spinal cord injury in a medical rehabilitation hospital are participating in a model reentry program for a 4-month period, whereas the next 50 inpatients will receive conventional reentry services. This cycling of model and conventional services will continue over a 2-year period. The experience of participants in both the model and conventional groups will be surveyed by telephone and follow-up mailed questionnaires at 2, 6, 12, and 24 months post-discharge. Data will be collected and analyzed from measures of reported occurrence of complications, such as decubitus ulcers or urinary tract infection; psychological independence, by the Personal Independence Profile; disability status, by the Functional Independence Measure; psychological well-being, by the Center for Epidemiologic Studies Depression Scale; the Perceived Stress Scale; health maintenance activities, by the reported adherence to skin and genitourinary self-management; service utilization, by independent living center contacts, physician visits, or total days of rehospitalization; and aspects of handicap such as social integration, productivity, and economic self-sufficiency, by the Craig Handicap Assessment and Reporting Technique.

[238] Innovative Strategies for Delivering Independent Living Services to Minority Persons with Disabilities: A Neighborhood-Based Approach

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Sponsor: National Institute on Disability and Rehabilitation Research

Purpose—ILRU is collaborating with the Houston Center for Independent Living (HCIL) to develop and demonstrate the feasibility of neighborhood-based independent living service delivery that will

result in enhanced vocational and independent living outcomes for minority persons with disabilities. Methods being used to implement neighborhood-based service programs include peer counseling,

community support network development, independent living skills training, and other traditional vocational rehabilitation service delivery approaches.

Progress—Four neighborhoods with large percentages of minority persons have been identified, and leaders of their neighborhood organizations, as well as precinct judges, have been contacted. Materials describing the project in plain language have been developed, and information for Hispanic neighborhoods has been translated into Spanish; these materials have been distributed in the target neighborhoods. Community meetings are being held in each neighborhood in churches, senior centers, libraries, civic clubs, and city-operated facilities about such topics as employment opportunities and resources for accessing those opportunities, transportation services and how to use them, housing options and assistance in obtaining housing, recreational options, and social activities. These meetings also present information on disability rights, antidiscrimination laws, and methods for seeking redress when discrimination is suspected.

Four persons with disabilities from each neighborhood have agreed to serve on a neighborhood

advisory committee. Recreational programming specialists, transportation specialists, employment counselors, and other resource persons have been scheduled to deliver services in each neighborhood. Individuals in each neighborhood have been selected and trained by project staff on disability rights, independent living concepts, and community services available to people with disabilities, to prepare them to serve as a neighborhood-based resource persons. Baseline data from individuals with disabilities in these communities is currently being collected using a two-page questionnaire excerpted from ILRU's comprehensive survey on personal independence, designed to determine levels of involvement in community activities. This community involvement survey will be readministered to persons with disabilities to determine if levels of community involvement have changed since participation in the community-based programs. In addition, a followup neighborhood resource survey will be conducted to determine if the resources available in each community to promote enhancement of vocational and independent living outcomes have increased, decreased, or remained the same since the start of the project.

[239] Wichita Rehabilitation Engineering Center

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—The Wichita Rehabilitation Engineering Center is a consortium of the Cerebral Palsy Research Foundation of Kansas (CPR) and the Wichita State University College of Engineering. It is mandated by its funding agency, the National Institute on Disability and Rehabilitation Research, with the enhancement of the vocational opportunities of persons with severe disabilities.

Assistive device centers are one of the latest trends in rehabilitation services and have been in existence for some time. Benefits to consumers are, for the most part, immediate and obvious, but data analysis of these operations and their transactions often is secondary to daily activities or is completely ignored.

Funding was obtained in 1989 to initiate an assistive device center at CPR. The Center is expected to provide savings to Kansas social service funding agencies, whose clients are able to try out devices in advance of their purchase. A database is being developed to track transactions, client-specific data, and information relative to device utility.

Results—The Center for Assistive Resources at CPR has been in operation for 2 years. Although a database has yet to be perfected, certain pertinent information has been collected regarding commercially available products and transactions.

A typical person who uses this service will not initiate a device search on his or her own and, in

most cases, must be prompted to visit the Center by a vocational rehabilitation counselor or service coordinator. In addition, consumers visiting CPR to receive other services frequently stumble upon the Center while awaiting service. Consumers who visit the Center usually have a specific problem and are seeking relief in performing a specific function. It is common for consumers to leave the Center with some type of device, whether or not their original problem was addressed or resolved.

Virtually half of all devices available through commercial sources are related to some type of hand functioning and half deal with food preparation. The lack of devices related to other aspects of daily living reflects the lack of confidence on the part of manufacturers in pursuing products that may have a very limited market. Products related to clothing/sewing, educational management, and recreation/

leisure activities have been identified by the Center director as having potentially large markets.

One important feature of the Center is an indigent client program that provides funding for devices to those who cannot afford them. Depending on the outcome of a needs test, clients are provided with appropriate technology free of charge, consistent with the financial resources of the program. The program is limited to Kansas residents only on a first-come, first-served basis.

Future Plans—More efficient data collection procedures will enable the Center to better track transactions and rate the utility of devices. In addition, product demonstrations are being scheduled on a regular basis to help stimulate awareness and interest.

[240] Rehabilitation Engineering Center

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Sponsor: National Science Foundation; Texas Department of Mental Health and Mental Retardation

Purpose—This program provides rehabilitation engineering consultation at state Mental Health and Mental Retardation facilities, schools, and other sites utilizing bioengineering faculty, bioengineering students, and special education students. The program provides for design and modification projects which benefit individual clients or are used within the facility for client treatment or education. Technology workshops are also provided. In addition to direct services, the program is also intended to enhance the rehabilitation technology capabilities of present and future practitioners.

Progress—This is an ongoing program. Initial efforts consist of meetings at each facility to acquaint the staff with the program and the types of projects which would be consistent with available resources. This is followed by frequent meetings to identify and implement projects. A wide array of electronic and mechanical devices have been designed and delivered under this program. In addition, design and electronics workshops have been conducted to enhance the technical skills of on-site personnel.

Results—The direct result of this work is the delivery of new or modified adaptive equipment directly into the rehabilitation and special education settings. Communication devices for nonverbal and motor-limited clients have been developed which allow for simple selection from a limited menu using a variety of input devices. Additional projects included several types of interfaces between clients and environmental devices, and prevocational training devices which provide a reward feedback for completed tasks. Sheltered workshop task design problems were addressed to improve workers' efficiency, and to bring new contracts to the workshop. A laser emitter system used as a head pointer has been developed to replace cumbersome incandescent versions. This improves communication skills of disabled clients by allowing pointing to remote areas without adverse effects of ambient light. Laser sensors have also been developed to allow the head-mounted emitters to activate various DC- and AC-powered devices. Several postural feedback systems were provided, including one using a zero-force shadow switch and various low-force pressure switches.

A variety of innovative physical therapy and occupational therapy equipment has been developed, including a pronation/supination training aid, a bilateral walking force measurement and feedback system, and an object warning system for canes and walkers for blind clients.

Future Plans/Implications—Experience with this program has demonstrated that there is an ongoing need for engineering design input for a variety of client problems at these facilities. The service model has advantages in that continuous engineering services could not be effectively utilized by these facilities at this time. Moreover, this program includes an array of expertise and experience and the resources of the University for fabricating projects.

Future plans include expanding the program to cover more state and school facilities. Technology training for therapists and teachers will also be further developed. For the engineering student, this program provides an opportunity to solve real-world problems and obtain understanding of individuals with handicaps and their needs.

Recent Publications Resulting from This Research

Application of Force Sensitive Resistors. Hyman WA, Miller GE, in Proceedings of the 13th Annual RESNA Conference, Washington, DC, 1990.
Adaptive Equipment Design for Special Education by Interdisciplinary Undergraduate Students. Hyman WA et al., in Proceedings of the 14th Annual RESNA Conference, Kansas City, MO, 1991.

[241] Feasibility of Establishing a Regional Personal Assistance Program in the Washington, DC Area

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Sponsor: *Robert Wood Johnson Foundation*

Purpose—This project aims to determine the feasibility of establishing a model personal assistance program in the Washington, DC region. The problem of acquiring adequate attendant care is a major and unrelenting concern to many persons with severe physical limitations. Many factors contribute to this problem, most significantly the lack of adequate funding and benefits for attendants. However, other factors are also critical, including a lack of understanding of which groups of persons in society are most likely to supply attendants, what attitude barriers exist to recruiting attendants, and what aspects of the interpersonal interaction between attendant and consumer are significant in the retention of attendants. In this study, these factors are being analyzed with the goal of designing a system that reflects a more sophisticated approach to these supply-side issues.

Progress/Methodology—This study uses a three-pronged approach to collecting information on recruitment and retention of attendants: focus groups, personal interviews, and review of existing regulations/requirements governing personal attendant use. In focus groups, attendants and consumers have provided information on recruitment, training,

qualifications, communication barriers, reimbursement, interpersonal relations, and many other aspects of the attendant care relationship. Focus groups of persons from potential sources of attendants (e.g., students, the elderly, immigrants, and persons with cognitive disabilities) are clarifying issues which must be addressed in recruiting from different groups.

The first phase of the feasibility study has been completed and the second phase commenced in September 1991. In the first phase, focus group findings allowed for clarification of issues that will be explored more fully in phase two.

Preliminary Results—Significant cultural and communication barriers must be overcome to recruit from some ethnic groups. Retired persons are more likely to be interested in attendant care positions if the positions do not require significant physical exertion, and if the retired person has some previous experience in a related field. Linking persons with cognitive disabilities to attendant positions for persons with physical disabilities will require the development of careful screening criteria and may require ongoing external support.

[242] Assessing the Capabilities of Independent Living Center Staff to Deliver ADA-Related Services

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Sponsor: U.S. Department of Education

Purpose—Since the passage of the Americans with Disabilities Act (ADA), independent living centers have been getting requests for information from persons with disabilities who want to know what ADA will mean to them, and from employers, businesses, and service organizations who want to know what will be required to comply with the new law. ILRU will investigate the following questions:

- How much information about ADA do independent living center management and direct service staff have available to them?
- What information gaps relative to ADA and plans for its implementation exist in the independent living field?
- What misconceptions or incorrect perceptions concerning ADA do independent living center staff hold?
- What resources are being used by independent

living center staff in providing ADA-related information to various audiences?

- For which aspects of ADA and its implementation are information resources inadequate or lacking?
- What questions concerning ADA are most frequently asked by service consumers with disabilities, and how comfortable are center staff in answering these questions?
- What questions concerning ADA are most frequently asked by employees, businesses, and community service organizations, and how comfortable are center staff in providing answers to these questions?
- What legislative compliance problems are most frequently encountered by employers, businesses, and community service organizations for which center staff can suggest no solutions or are unsure of the best solution?

[243] Effect of Personal Assistance Services on Productivity and Daily Living among Japanese with Severe Physical Disabilities

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Sponsor: World Rehabilitation Fund

Purpose—The purpose of this study was to pilot test a methodology for assessing arrangements through which persons with disabilities obtain personal assistance to compensate for their functional limitations, levels of satisfaction with these services, and the effect personal assistance services have on their productivity and daily living.

Progress—Thirty subjects were recruited from the Tokyo and Kansai areas with the assistance of the Human Care Association—an independent living center in Tokyo—and organizers of the Ninth

Annual Conference of Wheelchair Users, held September 1989, in Hyogo, Japan. Each individual completed a written questionnaire consisting of demographic data, the Personal Assistance Satisfaction Index (PASI), and the DeJong Productivity Scale. Of this sample, 15 were also interviewed in person. A summary of the results has been translated into Japanese for publication in Japan.

Results—The most common disability represented was cerebral palsy, followed by quadriplegia from spinal cord injury, then muscular dystrophy. Of the

majority, who lived with family (73%), only family provided assistance in 40%, only nonfamily did in 20%, and a combination assisted in 12%. The second most common arrangement was living alone (27%), in which nonfamily members, usually paid workers, provided assistance (24%). No one lived with nonfamily. The average amount of personal assistance used was 11 to 20 hours per week. Regarding payment for services, 44% received assistance free, 16% used their own funds, 12% used government-paid assistance only, 12% used a combination of free and government-paid assistance, and 16% used their own funds combined with free assistance. More than three-quarters of the subjects (78%) indicated that they were dissatisfied with both the availability and the cost of personal assistance. Those who lived alone but used nonfamily assistants had the highest level of satisfaction, while those who lived with family but had nonfamily assistants had the highest level of productivity. Individuals who were among the most satisfied were more likely to be married and to have nonfamily, paid assistants. Individuals who were among the most productive also tended to be married, older, and less educated.

Anecdotal data indicated a strong desire to have more control over arranging personal assistance, greater availability of persons to serve as assistants, and more funds to pay them. Of the 15 subjects interviewed in person, 11 said they preferred family or hired persons as assistants. Those favoring family said that they felt more free to ask for the assistance they needed and that the quality of assistance was better because family knew them so well. Those who preferred hired personal assistants cited control over the selection of the assistant and the scheduling of assistance. Subjects who received assistance from the Home Helper system unanimously expressed dissatisfaction with their inability to choose the assistant and the patronizing attitude of the assis-

tant. Eight subjects commented that they lacked enough personal assistance to achieve the level of productivity they desired. Reluctant to ask for the extent of assistance actually needed from family, many felt that they must sacrifice their productive aspirations to minimize the burden on their family.

Only a small portion of Japanese citizens with disabilities are competitively employed, which reflects not only a lack of appropriate assistance services, but also their exclusion from the mainstream educational system, as well as the negative attitudes of employers toward people with disabilities. Separate educational facilities fail to equip them with the social and educational skills necessary to compete in the real working world. In addition, architectural and transportation barriers limit their mobility in the environment. Consequently, the primary activities reported were volunteer work or participation in sheltered workshops.

Implications—The results of this study strongly suggest the need for national policies on personal assistance services in both Japan and the United States, as well as a commitment to establish national programs that offer broad personal assistance services at a reasonable cost and with a range of options for consumer control of the services. Only then can persons with physical disabilities realize their full potential for productivity in the community.

Recent Publications Resulting from This Research

Personal Assistance Services in Japan: Effect on Productivity and Daily Living among Japanese with Severe Physical Disabilities. Nosek MA. New York: World Rehabilitation Fund, Inc., 1990.

Relationships between Personal Assistance and Productivity among Japanese with Severe Physical Disabilities. Nosek MA, Rehabil Counsel Bull 34, 1991.

VIII. Muscles, Ligaments, and Tendons

A. Muscles

[244] Back Pain: Biomechanical and Myoelectric Events During Fatigue

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Sponsor: *VA Rehabilitation Research and Development Service (Project #B593-RA, Part 1); Liberty Mutual Insurance Company*

Purpose—The Electrophysiology Laboratory was recently established at this Center to gain a more detailed understanding of how biochemical changes associated with fatigue influence the behavior of the median frequency and conduction velocity estimates of the electromyography (EMG) signal. The studies to be conducted in this laboratory represent a continuation and further development of previous collaborative studies with the Pulmonary Center of Boston University School of Medicine and the Boston VA Medical Center. Our goal is to pursue *in vivo* investigations of fatigue in neuromuscular preparations from small rodents.

Methodology—The preparations are typically placed in a highly controlled experimental chamber filled with a physiologic solution. A specialized array of surface EMG electrodes is placed on the muscle strip to monitor EMG signal spectral parameters and conduction velocity from electrically elicited contractions. A supermaximal voltage is applied to the nerve to elicit a maximal sustained stimulated contraction. By artificially altering a specific component of the bathing solution and recording the resultant effects on the EMG signal, we hope to establish a more direct and causal relationship between biochemical and electrical events associated with fatigue. *In vitro* studies are being planned in animals to complement human *in vivo* studies which

are less able to establish causality in describing biochemical-electrical relationships.

Progress—In the process of establishing a new laboratory, we modified several key aspects of the experimental set-up. A new analog-to-digital (A/D) processing system was developed which now facilitates EMG signal and muscle force processing during data collection. We have also improved our pH monitoring system, and implemented the standard force transducer technology developed at the NeuroMuscular Research Center.

Preliminary Results—Our most recent reports from these investigations established a causal relationship between muscle pH and the EMG signal in the hamster diaphragm muscle. We are currently repeating that study in two different hind limb muscles of the rat. In a recent series of preliminary trials we successfully recorded EMG signals from both the EDL and soleus muscles. The distinct fiber type composition of these muscles makes it possible to study the influence of muscle histochemical properties on the behavior of electrical and contractile parameters during elicited muscular fatigue.

Recent Publications Resulting from This Research

Biomechanical and Myoelectrical Events During Fatigue. De Luca CJ, et al., presented at the Eighth Congress of the International Society of Electrophysiological Kinesiology, Baltimore, MD, 1990.

[245] Back Pain: Back Assessment of Athletes from Varsity and Freshman Crew Teams

Carlo J. DeLuca, PhD; Mark Emley; Serge H. Roy

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Sponsor: VA Rehabilitation Research and Development Service (Project #B593-RA, Part 2); Liberty Mutual Insurance Company

Purpose—The purpose of this study is to determine whether electromyographic (EMG) spectral parameters from lumbar muscles can correctly identify individuals with low back pain (LBP) within a mixed population of novice and experienced freshman rowers. A similar study had previously been successful in identifying LBP within a group of varsity rowers with and without LBP. Tests using the Back Analysis System (BAS) are being conducted twice a year on members of the Boston University crew teams until they complete their varsity year. Our objective is to compare development of LBP and gains in physical strength and rowing performance with EMG measures of back muscle function. Results from this investigation will be helpful in identifying whether EMG measures of back muscle insufficiency can identify a predisposition to LBP. Crew members have been targeted for this study because they share similar physical characteristics and are exposed to strenuous lower back activities.

Preliminary Results/Future Plans—Forty members of the Boston University men's freshman crew team have participated in this study to date. As new freshman crew members join the team, they will be

recruited for the study. Upon retesting of the novice crew members following a winter training period, there was an increase in static strength of back extensor muscles and a greater resistance to fatigue as measured by the EMG signal. The experienced rowers did not show a significant gain in either of these measures but instead maintained their high level of function. These findings indicate that extensive training and level of fitness has a measurable effect on the EMG signal. Since this is a prospective study requiring several more years of study, predictive results must await further data collection. Future testing will include rowers from other universities and rowing clubs.

In the fall rowing season of 1990, we also tested eight members of the women's varsity crew team. Preliminary findings indicate asymmetries in muscle endurance capacity and a high incidence of back pain. Further testing of women crew members are planned to establish norms among women athletes, and for comparison to their male counterparts.

Recent Publications Resulting from This Research

Fatigue, Recovery, and Low Back Pain in Varsity Rowers. Roy SH, et al., *Med Sci Sports Exerc* 22(4):463-469, 1990.

[246] Back Pain: Comparison of Spinal Mobility and Isometric Trunk Extensor Strength to EMG Signal Spectral Analysis in Identifying Low Back Pain

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Sponsor: VA Rehabilitation Research and Development Service (Project #B593-RA, Part 3); Liberty Mutual Insurance Company

Purpose—This study compares the ability of traditional clinical tests of spinal mobility and trunk extensor strength to electromyographic (EMG) signal spectral analysis techniques in identifying individuals with lower back pain (LBP).

Methodology—Twenty-five members of the Boston University freshman crew team were subjects for this study. Trunk range of motion (ROM) measurements were taken using standard clinical procedures and the Back Analysis System (BAS) was used to

determine trunk extensor strength and assess changes in muscle fatigability by EMG measurements.

Results/Implications—The ROM and strength measurements correctly identified 57% of the crew members with LBP and 63% of the non-LBP crew

members. In contrast, the EMG parameters correctly identified 88% of crew members with LBP and 100% of the non-LBP crew members. These results indicate that EMG techniques may be a better screening and diagnostic procedure for LBP than some conventional methods.

[247] Back Pain: Low Back Pain and Muscle Fatigue

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Sponsor: VA Rehabilitation Research and Development Service (Project #B593-RA, Part 4); Liberty Mutual Insurance Company

Purpose—As many as 75 million Americans now suffer from severe lower back pain and each year seven million more people develop this problem. Despite the many millions of dollars spent on innumerable treatments for the back, the majority of patients have chronic, recurring symptoms. Improved methods of assessing back disorders could help to diminish the prevalence and the financial burden of this disabling condition.

Progress/Methodology—We have developed, and are implementing, a technique to provide clinicians with an objective index with which to measure treatment outcome for lower back musculature. This technique estimates the fatigue rate of contracting muscles by using surface-detected electromyography (EMG) signals. The dynamic interaction of synergistic back muscles during fatiguing contractions may be represented by "fatigue patterns" created by the frequency shifts in various muscles. Differences in these patterns associated with low back disorders may represent functional disturbances in back muscles.

The EMG measurement technique for the lower back was recently redesigned to meet the needs of the clinical environment where it is presently used as a research instrument. This technique is called the Back Analysis System (BAS). Our goal is to develop

a database large enough for future diagnostic capabilities. Numerous tests are being conducted at several clinical sites using a standardized protocol that includes both high and low force levels of contraction. Clinicians from two of the clinical sites, Braintree Hospital and Liberty Mutual Medical Service Center, have been trained to conduct the test protocols using the BAS. The technique is specifically being evaluated in these two sites as a treatment outcome measure for their full-time work-hardening program for low back pain patients. A computerized database program has been written to organize the data for further analysis.

Our assessment technique targets specific sub-categories of low back pain. Unlike our previous pilot studies, we are including more aged subjects and female subjects in these tests. A disability survey and pain questionnaire have been included in the standard protocol. Conventional measures of spinal mobility and static strength have been obtained and compared to EMG median frequency measurements.

Preliminary Results—Our results to date indicate that the EMG parameters are able to discriminate low back pain patients from pain-free control subjects, whereas conventional methods do not.

[248] Back Pain: Incidence of Falls and Back Pain in the Department of Veterans Affairs

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Sponsor: VA Rehabilitation Research and Development Service (Project #B593-RA, Part 5); Liberty Mutual Insurance Company

Purpose—The purpose of this research is to derive estimates of the burden of care presented to the VA system by the clinical problems of “falling” and “back pain.”

Progress/Methodology—We analyzed the 1989 and 1990 Patient Treatment File (PTF), a VA secondary database. The PTF provides lists of episodes of hospitalization with the discharge diagnoses. Inferences about levels of outpatient care, although less accurate, can also be drawn from this data.

It must be noted that while “medical back pain” is a specific medical diagnosis (DRG 243), falling is a symptom, rather than a diagnosis. Since it is a reason for hospitalization, it is in a special category of “E” codes (E8800-E888). While the presence of this code may be very specific (i.e., people who do not fall are very unlikely to have this code as part of their record), it may not be very sensitive (i.e., people who do fall may instead be coded solely by the final diagnosis, such as “hypotension”).

Results—For the VA nationally, 27,567 individuals had at least one discharge with a diagnosis for “low back pain,” while 10,110 individuals were hospitalized at least once with an E code indicating the problem of falling. In each case, the 61 to 70 age group contributed the greatest number to the total, with 7,374 (26.6%) reporting low back pain, and 3,308 (32.7%) reporting falling.

Falling seems to be highly related to diagnoses noted for their morbidity and cost. An analysis was conducted to look at the leading diagnosis (i.e., the major cause for hospitalization) when the record indicated the problem as falling. The four most common diagnoses are all major orthopedic diagnoses, totalling 1,903 (18.83%) cases. Within the 50 most frequent diagnoses, 4,000 cases (38%) involved major orthopedic conditions such as hip fracture or surgery, or fractured legs or arms.

The most common medical diagnosis was medi-

cal back problems, with 381 patients (3.66%). The most common psychiatric diagnosis was psychoses, with 310 patients (2.98%). Multiple diagnoses in the top 50 related to alcohol and drug use, and detoxification, contributed 845 patients (8.1%).

The elderly are disproportionately represented in the number of diagnoses related to falls. The group with ages greater than 80 contributed a total of 9.4% of cases with falls. However, they represented 19.3% of the cases with hip fracture, 15.5% of the cases receiving a major joint procedure, 19% of the cases with organic mental disturbances and mental retardation, 25.4% of the cases with heart failure and shock, 14.9% of the cases with pneumonia, and 20.3% of the cases with miscellaneous metabolic disorders.

We also evaluated the relationship of four specific diagnoses—degenerative nervous system disease, major joint procedure, hip or femur procedure, and fractures of hip and pelvis—to falls. Falls would be expected to be associated with these diagnoses based on clinical criteria.

Altogether, in 1990, 6,056 patients were discharged with a first diagnosis of nerve degeneration. Of these, only 83 patients (1.4%) also had a code for falling. Most of these 65 patients (78%) were for an unspecified accidental fall.

A major-joint procedure was the first diagnosis on 4,477 patients, of whom 374 (8.4%) were coded as having fallen. Again, most reported an unspecified accidental fall (239, or 63.9%), while most of the remainder (64, or 17.1%) had slipped, tripped, or stumbled on the same level.

Fractures of the hip and pelvis represented the first diagnosis for 1,041 patients, 473 of whom (45.4%) also were coded for falling. Hip or femur procedure was first diagnosis for 1,453 patients, of whom 685 (47.1%) were also coded for falling. The distribution of types of falls was similar to the above results. Within the greater-than-80 age group, the distribution of types of falls also remained about the same.

[249] Back Pain: Back Analysis System (BAS Update)

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Sponsor: VA Rehabilitation Research and Development Service (Project #B593-RA, Part 6); Liberty Mutual Insurance Company

Purpose—During the past 4 years, we have continuously refined the methods used to evaluate muscle performance in individuals with and without lower back pain. A key component in these investigations has been the Back Analysis System (BAS): a computerized electromyographic (EMG) spectral analysis system coupled to a pelvic restraining device.

Methodology—The BAS and its associated apparatus is designed to stabilize and isolate the trunk musculature and analyze the patterns of muscle activity observed during isometric fatiguing contractions of the back. The specialized restraint apparatus is designed to immobilize the pelvis and assure

that the contribution to the flexion and extension forces are limited to the muscles of the lower back.

Progress/Implications—Currently, BASs are installed at several clinical sites exploring the integration of this technique with clinical assessment and treatment protocols for muscular disorders. This year, additional systems are scheduled to be fabricated for more extensive clinical evaluation of the device. The knowledge gained from these trials will lead to better understanding of the role that this technology will play in the clinical assessment of muscular performance and dysfunction in the lower back.

[250] Motor Control Deficiencies: Synchronization of Motor Unit Discharges

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Sponsor: VA Rehabilitation Research and Development Service (Project #B594-RA, Part 1); Liberty Mutual Insurance Company

Purpose—Synchronization has been somewhat of a mystery to researchers for the past two decades. Conflicting answers have been given to what seem to be rather simple questions: does synchronization exist; to what degree does it exist; what causes synchronization; and what effect does it have on normal muscle contractions? Our group has been studying synchronization for more than 6 years. Recent refinements to our analysis techniques, as well as some new ideas, have helped us to answer some of these questions and have brought us closer to solving the synchronization mystery.

Synchronization is the tendency of two or more motor units (MUs) to fire at a fixed latency, more often than would be expected than if the MUs were to discharge independently. When the firing times of one MU are plotted with respect to the firing times of another, in the form of a Cross-Interval Histogram, synchronization manifests itself as a peak in

this histogram. The degree of synchronization as well as its modality can be measured by the size of this peak and the latency at which the peak occurs.

Progress/Results—Some of our findings include the following: Synchronization is evident in many different muscles in upper and lower extremities. When it occurs, it takes place to the same degree in each muscle. Synchronization appears to occur in two modalities; peaks that occur at short latencies, which represent two MUs that are firing simultaneously; and peaks that occur at longer latencies, which represent one MU firing at a fixed delay with respect to another. Synchronization at short latencies is more frequent than synchronization at long latencies. Finally, although synchronization occurs in most muscles, it seems to have little effect on overall muscle function.

[251] Motor Control Deficiencies: Synchronous Firing and Drive Behavior Among Motor Units in Aged Adults

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Sponsor: VA Rehabilitation Research and Development Service (Project #B594-RA, Part 2); Liberty Mutual Insurance Company

Purpose—This study endeavored to determine whether the control of groups of motor units is different in college-aged individuals than in aged adults.

Progress/Methodology—Motor unit recordings were obtained from the first dorsal interosseous (FDI) and tibialis anterior (TA) muscles in college-age (18–30 yrs) and aged (65–100 yrs) adults. The subjects were asked to perform slow, isometric contractions by following a trajectory that was traced on a monitor, reaching a force maximum of 30–50% of maximal effort. Motor unit recordings were made using quadrifilar electrodes and the resultant signals were decomposed, yielding multiple motor unit action potential trains. The results indicated that similar 1–2 Hz fluctuations in motor

unit firing rates (common drive behavior) were observed in both groups. One older subject demonstrated grouped, motor unit “bursting” behavior. However, we observed similar levels of motor unit synchronization in both aged and young adults. So, although our previous reports presented some evidence of irregular motor unit recruitment in older individuals, several aspects of motor unit firing behavior appear to be similar in both young and old adults.

Recent Publications Resulting from This Research

Synchronous Firing and Common Drive Behavior Among Motor Units in Aged Adults. DeLuca CJ, Kamen G, Roy A, presented at the combined sections meeting of the Annual Conference of the American Physical Therapy Association, New Orleans, LA, March 1990.

[252] Motor Control Deficiencies: Firing Rate Behavior Among Human Orbicularis Oris Motor Units

Carlo J. DeLuca, PhD; Gary Kamen

NeuroMuscular Research Center, Boston University, Boston, MA 02215; VA Outpatient Clinic, Boston, MA 02114

Sponsor: VA Rehabilitation Research and Development Service (Project #B594-RA, Part 3); Liberty Mutual Insurance Company

Purpose—Our previous investigations have demonstrated that groups of human motor units from the same muscle exhibit joint fluctuations in firing rate during voluntary muscle contraction. One possible source of this “common drive” behavior is the human muscle spindle receptor. In an effort to determine whether similar behavior would be observed in a muscle in which muscle spindles are absent, motor unit firing behavior was examined in the human orbicularis oris interior (OOI) during mild voluntary muscle contraction.

Methodology/Results—Motor unit activity was recorded from the OOI and firing occurrences were identified using our motor unit decomposition pro-

cedure. Cross-correlation of motor unit firing rates revealed a tendency for motor unit firing rates to co-vary, although the effect was more variable than that observed previously in other skeletal muscles. Analysis of synchronous firing behavior revealed that there was also a statistically significant tendency for pairs of motor units to fire at simultaneous or near-simultaneous (± 5 ms) intervals (“synchronization”), similar to that seen in the first dorsal interosseous (FDI). The variability of interpulse intervals in OOI motor units was not significantly different ($p > 0.05$) from that observed in the FDI. Thus, the present results seem to strengthen the argument for a more central site underlying the common drive of human motor units.

[253] Motor Control Deficiencies: Interactions Between Human Motor Unit Recruitment and Discharge Behavior—Effects of Topical Anesthesia

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Sponsor: VA Rehabilitation Research and Development Service (Project #B594-RA, Part 4); Liberty Mutual Insurance Company

Purpose—The purpose of this research was to study motor unit firing behavior in the human first dorsal interosseous (FDI) muscle during controlled isometric contractions.

Methodology/Results—Force recruitment thresholds and firing rates were monitored following the application of an anesthetic applied topically to the hand and forearm skin. The force at which motor units were recruited was altered by the anesthetic treatment such that the recruitment threshold of the low-threshold units was raised, while the recruitment threshold for the high-threshold units was lowered.

Motor unit discharge rates were also affected by the topical anesthetic. Those units with low firing rates prior to drug treatment increased their firing rates, while motor units with high discharge rates (typically low-threshold units) manifested a reduction in firing rate. The relationship between discharge rate and recruitment threshold was maintained throughout the experiment, even as both parameters were altered by the attenuated cutaneous input. These results suggest a tight coupling between motor unit recruitment threshold and mean firing rate. This relationship is maintained, even as the sensory input to the motoneuron pool is altered.

[254] Motor Control Deficiencies: Effects of Percutaneous Stimulation on Motor Unit Firing Behavior in Man

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Sponsor: VA Rehabilitation Research and Development Service (Project #B594-RA, Part 5); Liberty Mutual Insurance Company

Purpose—Increasing evidence suggests that neural receptors located in the skin play a major role in motor control. We conducted an experiment to determine whether increased activation of skin receptors would alter motor unit firing behavior during controlled, constant force isometric contractions in a small hand muscle, the first dorsal interosseous (FDI).

Methodology/Results—The threshold at which motor units were recruited, and the mean firing rate at 50% of maximal voluntary force (MVC), were evaluated following stimulation of the skin area over the second digit. Stimulation of cutaneous receptors tended to increase the recruitment threshold of most

of the motor units recruited under 20% MVC, while high-threshold motor units (those recruited over 30% MVC) generally exhibited a decrease in recruitment threshold. Less dramatic changes in motor unit firing rates were observed, but those motor units recruited over 30% MVC exhibited some increase in firing rate. We conclude that input from skin receptors is a potent modifier of the threshold force at which motor units are activated.

Recent Publications Resulting from This Research

Effects of Percutaneous Stimulation on Motor Unit Firing Behavior in Man. DeLuca CJ, Kamen G, Masakado Y, presented at the Eighth Congress of the International Society of Electrophysiological Kinesiology, Baltimore, MD, August 1990.

[255] Motor Control Deficiencies: Compartmentalization in the Human Tibialis Anterior Muscle

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Sponsor: VA Rehabilitation Research and Development Service (Project #B594-RA, Part 6); Liberty Mutual Insurance Company

Purpose—An intriguing concept being considered by researchers in Motor Control today encompasses the idea that muscles may be organized into distinct neuromuscular compartments, each compartment consisting of the muscle fibers innervated by the primary branches of the nerve to a muscle. This study sought to investigate this possibility by studying the independence of motor unit action in different regions of the human tibialis anterior (TA) muscle.

Methodology/Results—Motor unit recordings were obtained from the TA using two quadrifilar needle electrodes spaced 5 to 6 cm apart. The multichannel recordings were made while the subject performed an isometric contraction at 30 percent of maximal effort. Motor unit firing histories from within each needle site and between the two sites were studied to determine the frequency of simultaneous (synchronous) discharges, as well as to determine the level of

common fluctuation of firing rates. We observed considerable synchronized firing at zero or near-zero latency from units recorded in both distal and proximal needle sites and a similar level of synchronous firing among units measured between the two sites. Also, the fluctuation of firing rates was similar among distal, proximal, and between-needle motor units, with cross-correlations of firing rate trains of about 0.6 obtained in each case.

Implications—Our results would appear to support the existence of a strong central command to all motor units within a given muscle, without regard to anatomical location.

Recent Publications Resulting from This Research

Compartmentalization in the Human Tibialis Anterior Muscle. DeLuca CJ, et al., presented at the Twentieth Annual Meeting of the Society for Neuroscience, St. Louis, MO, November 1990.

[256] Motor Control Deficiencies: Effects of Stimulus Characteristics and Movement Distance on Coincidence-Anticipation Timing

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Sponsor: VA Rehabilitation Research and Development Service (Project #B594-RA, Part 7); Liberty Mutual Insurance Company

Purpose—The ability to accurately time the performance of a motor response coincident with the receipt of a visual stimulus is an important motor skill used in gross motor tasks, such as catching a ball or steering an automobile, as well as fine motor skills, such as washing dishes or performing assembly-line tasks. Although most coincidence-anticipation timing (C-A) tasks involve responses to either accelerating or decelerating objects, laboratory C-A experiments typically use constant-velocity stimuli, usually with a Bassin anticipation timer. In an effort to extend our knowledge of coincidence-anticipation

timing, we sought to explore the manner in which C-A is programmed using both constant-velocity and decelerative stimuli for both short (160 mm) and long (480 mm) movement tasks.

Methodology/Results—Sixteen right-handed subjects performed a horizontal arm movement in response to a visual stimulus presented on a video monitor. Both constant-velocity and decelerative stimuli were presented with equal duration (1.08 sec). We found that decelerative stimuli produced less error for long-movement tasks than for short-

movement tasks, and this effect was more marked when the nature of the stimulus (constant-velocity versus decelerative) was uncertain. The manner in which individuals respond in C-A tasks depended on the kinematic characteristics of the stimulus, and this needs to be considered in studies designed to measure anticipation timing in ecologically valid tasks.

[257] Motor Control Deficiencies: Fatigue Effects on Motor Unit Firing Behavior

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Sponsor: VA Rehabilitation Research and Development Service (Project #B594-RA, Part 8); Liberty Mutual Insurance Company

Purpose—Previous researchers have attributed the frequency shift in the surface myoelectric (ME) signal during a sustained contraction to a decrease in conduction velocity (CV) of the muscle's fibers. However, CV alone does not account for the simultaneous, large changes in the power spectrum of the surface electromyography (EMG) signal. This study examined the relationship between changes in firing behavior of active motor units and the concomitant changes in the frequency spectrum of the surface and cannula signals that accompany fatiguing contractions.

Methodology—Motor unit action potential trains (MUAPTs) were obtained from 14 young healthy subjects using a quadrifilar indwelling needle electrode. Subjects were asked to perform a constant force contraction of the tibialis anterior at 80% of

Recent Publications Resulting from This Research

Effects of Stimulus Characteristics and Movement Distance on Coincidence-Anticipation Timing. DeLuca CJ, et al., presented at the Annual Meeting of the American College of Sports Medicine, Salt Lake City, UT, June 1990.

their maximal force level. Spectral information was obtained from the surface-detected ME signal and the needle cannula ME signal. Spectral shifts were monitored by tracking the median frequency of the spectrum throughout the contraction. The mean firing rate and the level of synchronization were determined for each contraction.

Results/Implications—Our results showed that the greatest decrease in mean firing rate corresponded to the smallest decrease in the median frequency of both the cannula and bipolar surface signals. There was no consistent relationship between fluctuations in the median frequency and the amount of synchronization. It appears that mean firing rate changes and synchronization do not play a significant role in the median frequency changes that occur during fatiguing contractions.

[258] Motor Control Deficiencies: Visual Feedback Inhibits Kinesthetic Learning in Aged Adults

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Sponsor: VA Rehabilitation Research and Development Service (Project #B594-RA, Part 9); Liberty Mutual Insurance Company

Purpose—The visual sense tends to dominate the performance of motor skills, even when the use of kinesthetic information would result in faster or more accurate responses. There is some speculation that aged adults accentuate this focus on visual

information, even as their visual skills decline. This study was designed to study these two paradoxical observations and determine the joint role of kinesthetic and visual feedback in learning a force reproduction task.

Methodology—Maximal voluntary force of the first dorsal interosseous muscle, an index finger abductor, was tested in the preferred hand of aged (>65 yrs) and college-age subjects ($n=20$). Each individual was then asked to estimate and reproduce 20%, 40%, 60% and 80% of maximal force in a no-feedback condition. Subjects then performed 10 isometric contractions using visual feedback from a video monitor and force reproduction were then retested.

Results/Implications—An analysis of variance design revealed the presence of significant group \times pre-post interaction ($p<0.02$), demonstrating that

the young group improved following practice, while the older adults became less able to reproduce the required target force. These results seem to indicate that older adults place an increasing reliance on visual information, and suggest the need for retraining programs to improve motor performance.

Recent Publications Resulting from This Research

Visual Feedback Inhibits Kinesthetic Learning in Aged Adults. DeLuca CJ, et al., presented at the Motor Control Research Section of the American Alliance for Health, Physical Education, Recreation, and Dance, New Orleans, LA, April 1991.

[259] Motor Control Deficiencies: Nonmagnetic Force Feedback Display

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Sponsor: VA Rehabilitation Research and Development Service (Project #B594-RA, Part 10); Liberty Mutual Insurance Company

Purpose—In order to study changes in myoelectric signal parameters associated with biochemical changes occurring in the muscle tissue, our Center is using a technique called phosphorous nuclear resonance spectroscopy (NMR). This noninvasive method measures the characteristic "chemical signature" of the muscle tissue when subjected to strong magnetic and RF fields.

Methodology—These studies require subjects to perform sustained, constant level, isometric contractions of their leg muscles while lying in a reclined position in the field of the NMR magnet. During each contraction, simultaneous measurements of force, EMG, and NMR phosphorous spectra are recorded.

To minimize potential interactions between the strong magnetic fields required for NMR and the instrumentation required to detect EMG and muscle force, the Design Laboratory has fabricated a completely nonmagnetic force-measuring and feed-

back display system. The force transducer assembly, cables, and connectors are constructed using nonferrous materials. The subject's force feedback display consists of a linear array of light-emitting diodes and solid-state control circuitry. Because of severe space restrictions within the magnet, the feedback display module is located outside the magnet bore, just above and behind the head of the subject. The display, viewed with a small mirror positioned in front of the subject, provides the subject with a comfortable view of the force level while lying on his or her back within the narrow bore of the NMR magnet.

Progress—Presently, the nonmagnetic force feedback display system is being used in fibromyalgia studies conducted at Brigham and Women's Hospital, as well as for research being performed in conjunction with NASA at the Johnson Space Center in Houston.

[260] Motor Control Deficiencies: Design of a Leg-Referenced Ankle/Foot Restraint

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Sponsor: VA Rehabilitation Research and Development Service (Project #B594-RA, Part 11); Liberty Mutual Insurance Company

Purpose—The design of an “ideal” interface capable of isolating and accurately measuring the isometric torque produced about a human ankle joint is an engineering challenge. Any solution is a compromise between subject comfort, mechanical rigidity, and adjustment range suitable for fitting a diverse population. Our approach has been to couple existing commercially available knee/ankle brace technology with a custom-molded foot restraint apparatus developed at our Center. Evaluation of several prototype devices during the past year have demonstrated that this approach provides accurate measurement of ankle flexion and extension torques while maintaining the subject in a rigid, yet comfortable posture.

Progress/Methodology—A new addition to the apparatus this year is an instrument designed to measure the reference coordinates corresponding to the location of each electrode applied to the muscles

of the lower leg. This instrument, which attaches to the existing apparatus, insures that the exact position of each recording site can be duplicated, and greatly reduces the variability in data collection caused by inaccurate repositioning of the electrodes during subsequent EMG testing. The leg restraint apparatus, together with the electrode reference instrument, will be part of a system used to document the effect of prolonged spaceflight on muscle performance of the lower leg.

A completely nonmagnetic version of the apparatus, designed to be compatible with the strong magnetic fields associated with NMR spectroscopy, is presently being used to study the relationship between surface EMG and muscle metabolites on normal individuals and those with muscle dysfunctions. A third variation of the foot restraint apparatus will allow researchers to measure the “passive stiffness” of the human ankle joint system and its effects on postural stability as a function of age.

[261] Muscle Activation by Electrical Stimulation: An Index of Muscle Fatigue

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Sponsor: VA Rehabilitation Research and Development Service (Project #B595-RA, Part 1); Liberty Mutual Insurance Company; Politecnico di Torino; National Rehabilitation Council; Unita Socio Sanitaria

Purpose—Myoelectric signal variables and mechanical variables are known to change during sustained voluntary or electrically elicited contractions. These phenomena reflect changes in the properties of the muscle fiber and its membrane: such changes are generally referred to as “fatigue.” Muscle fiber conduction velocity and myoelectric signal spectral parameters (median and mean frequency) show a linear or curvilinear decrease in time, depending on the level of voluntary or electrically elicited contractions. Amplitude parameters (average rectified value and root mean square value) and force often show a

dome-shaped pattern with respect to time. In previous work, these patterns have been fitted with least square regression curves or lines whose parameters (decrement, time constant, initial slope, etc.) have been taken as indicators of the amount and rate of muscle property changes and, therefore, of ongoing fatigue.

A new index of fatigue is being proposed. The product of a reference value (e.g., the first value of the time series) and the time of observation defines a reference rectangle. The area between the upper side of such rectangle and the experimental data points is

divided by the area of the reference rectangle to provide this index. This area ratio index may be computed either as an attribute of a contraction or as function of time. It is regression-free and dimensionless. It varies between zero and one for decreasing patterns, it is negative for increasing patterns, and it is little affected by experimental point fluctuations, except for the value that defines the reference rectangle. With respect to other indices, the area ratio index provides a quantitative ap-

proach to fatigue that is consistent with the intuitive definition of fatigue. If applied to different myoelectric signal variables, the resulting area ratios may be interpreted as the components of a fatigue vector.

Recent Publications Resulting from This Research

Indices of Muscle Fatigue. DeLuca CJ, et al., *J Electromyog Kinesiol* 1(1):20-33, 1991.

[262] Muscle Activation by Electrical Stimulation: Myoelectric Manifestations of Muscle Fatigue in Elderly Subjects

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Sponsor: VA Rehabilitation Research and Development Service (Project #B595-RA, Part 2); Liberty Mutual Insurance Company; Politecnico di Torino; National Rehabilitation Council; Unita Socio Sanitaria

Purpose—The initial values and the time course of muscle fiber conduction velocity and of surface myoelectric signal spectral variables were studied during voluntary or electrically elicited contractions of the tibialis anterior muscle of 15 healthy elderly human subjects.

Progress/Methodology—The age range of the subjects was 65 to 84 years. Isometric voluntary contractions were performed at 20 percent MVC and 80 percent MVC for 20 sec. Tetanic electrical stimulation was then applied to the main muscle motor point for 20 sec with surface electrodes. Two stimulation frequencies (20 Hz and 40 Hz) and two stimulation amplitudes were used to induce different degrees of fatigue. One stimulation amplitude was supramaximal, the second was adjusted to induce an M-wave about 30 percent of the maximal. Results were compared with those reported in previous work

on healthy adults (ages ranging from 18 to 43 years).

Results/Future Plans—The main findings of this work are: 1) When the voluntary contraction level is increased from 20 percent MVC to 80 percent MVC, conduction velocity and spectral variables increase. Such increase is significantly smaller in elderly subjects. 2) During sustained contractions at 80 percent MVC, the decrease of conduction velocity and spectral variables is significantly smaller in elderly subjects. 3) During contractions induced by supramaximal stimulations at 40 Hz, the decrease of conduction velocity and spectral variables is not significantly different in the two age groups. We conclude that the first two findings reflect the age-related decrease of number and size of fast twitch fibers indicated by histological data. The third finding requires some additional investigation.

[263] Muscle Activation by Electrical Stimulation: Chronic In Vivo Recording of Neuromuscular Activity in the Rat Hindlimb by Indwelling EMG Electrodes

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Sponsor: VA Rehabilitation Research and Development Service (Project #B595-RA, Part 3); Liberty Mutual Insurance Company; Politecnico di Torino; National Rehabilitation Council; Unita Socio Sanitaria

Purpose—Researchers are only beginning to understand how increases and decreases in muscle loading regulate the adaptive response that results in muscle hypertrophy and atrophy, respectively. Quantitative and qualitative changes in skeletal muscle structure and function have been produced using surgical and mechanical intervention in the rat hindlimb. Colleagues at Boston University have been using this animal model to induce muscle hypertrophy by surgical ablation of synergist muscles. Similarly, muscle atrophy is induced by nonweight-bearing via hindlimb suspension.

One of the questions remaining in this work is whether change in muscle loading directly triggers adaptive response in muscle. Because change in muscle loading may also invoke change in neuromuscular activity, it is imperative that the pattern and amount of neuromuscular activity be measured during induced hypertrophy and atrophy.

Our involvement in this project is to develop an objective measure of neuromuscular activity in intact muscle from the rat hindlimb using indwelling EMG electrodes.

Preliminary Results/Future Plans—Although still in the development stage, we have been successful in recording EMG activity from the medial gastrocnemius muscle in a “control” caged rat for 42 days. Additional pilot studies are being conducted to increase our EMG detection capabilities to include other hindlimb muscles. Hardware is being fabricated to facilitate the detection and processing of EMG signals while the animals are tethered. Once our technical objectives have been successfully achieved, we will implement them in studies designed to understand the mechanisms that elicit adaptive responses in muscle.

[264] Muscle Activation by Electrical Stimulation: Characterization of Back Muscles by Means of Electrical Stimulation

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Sponsor: VA Rehabilitation Research and Development Service (Project #B595-RA, Part 4); Liberty Mutual Insurance Company; Politecnico di Torino; National Rehabilitation Council; Unita Socio Sanitaria

Purpose—Previous work on electrical stimulation of back muscles has indicated promise for the technique of muscle characterization. However, the complexity of the muscular layers of the back reduces the reliability and repeatability of the measurements. Objectives are to verify the conditions and to define quantitative criteria for easier separation of acceptable and unacceptable contractions. The conditions for meaningful measurements are: 1) the assessment of fatigue is performed on a motor unit population that remains stable during the

electrically elicited contraction; and, 2) the measurements performed on the same subject are reasonably repeatable.

Preliminary Results—The first condition was verified by checking for spectral compression of the myoelectric signal without change of spectral shape. The second condition was verified by repeating the same measurements five times in different days on each of three subjects. The first verification is somewhat subjective and very time-consuming.

A tentative quantitative criterion has been defined for easier separation of acceptable from unacceptable contractions. This criterion is based on changes that occur in the mean and median frequency of the myoelectric signals. It is reliable in classifying "good" contractions correctly, although some "bad" contractions are occasionally misclassified as "good." More reliable indicators of spectral shape change are being developed. At the present state of the art, two-thirds of the contractions can be accepted. Repeated measurements on

the same subject show coefficients of variation on the order of 2 to 10 percent for initial values, and 7 to 15 percent for fatigue indices.

Future Plans—This finding indicates that intrasubject-interexperimental repeatability is poor and repeated measurements will probably be required to reduce the role of random factors and allow detection of abnormalities. Experiments are underway to verify these preliminary findings and improve the techniques.

[265] Posture and Movement Stability: Biomechanical Design of Physical Therapy Exercises

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Sponsor: *VA Rehabilitation Research and Development Service (Project #B596-RA, Part 1); Liberty Mutual Insurance Company; Patricia Roberts Harris Fellowship*

Purpose—An accurate biomechanical model of the lumbar spine was developed which provides a valuable tool in understanding the lumbar musculature and may eventually aid in the diagnosis and treatment of low back pain. A method of evaluating the forces generated in the lumbar muscles was developed to test the accuracy of the biomechanical model.

Methodology/Results—Muscle force data were generated by the biomechanical model for different combinations of bending moments. The result was a four-dimensional space whose independent axes were the flexion, lateral bending, and torsion moments; dependent axis was the muscle force output for a particular muscle. To analyze the data, the torsion moment combination was set to a constant value, and the data were displayed as a contour map whose axes were the flexion moment axis and the right/left lateral bending moment axis. The curves constructing the contour map were termed "isoforce curves" and were defined by loading combinations

which produced a constant muscular force.

The experimental approach was designed to investigate the existence of the muscular isoforce curves using electromyographic and motion analysis technologies. A simple task, horizontal adduction of the arm, was designed which produced bending moment combinations that trace an isoforce curve on the contour maps of the erector spinae muscles. Experiments were conducted on five male subjects who performed this task. Surface electrodes recorded the EMG activity and the motion of the arm was monitored. The results suggest that muscular isoforce curves do exist, but vary among individuals.

Muscular switching curves were generated for each subject using data from the experiments. A switching curve is defined as the curve which separates the bending moment combinations which produce a muscle force from those which produce no muscle force. The individual switching curves were verified experimentally using static weight holding tasks.

[266] Posture and Movement Stability: Effect of Spinal Deformities on Lumbar Muscular Function

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Sponsor: VA Rehabilitation Research and Development Service (Project #B596-RA, Part 2); Liberty Mutual Insurance Company; Patricia Roberts Harris Fellowship

Purpose/Methodology—A biomechanical analysis was conducted to determine muscle activity resulting from the anatomical deformities due to scoliosis. A model was used to predict muscle contraction forces required to maintain equilibrium of the trunk in response to external flexion and lateral bending moments. The necessary input data are the muscle moment arms and lines of action. To generate input data, a graphics model of the musculoskeletal vertebral column was created. The model was manipulated to simulate the configuration of lumbar scoliosis. Using this method, it was possible to

acquire muscle geometry parameters for the normal and scoliotic spine.

Results—Results indicate that asymmetry of muscle geometry in scoliosis affects asymmetry of muscle function. In addition, the geometry alters the external lateral bending moments acting on the spine. The geometry of scoliosis commands asymmetry of muscle force and favors increased convex side muscle activity. Such asymmetry has been observed in previous electromyographic investigations of the paravertebral musculature of idiopathic scoliosis patients.

[267] Posture and Movement Stability: A Dynamical Systems Approach to Posturography

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Sponsor: VA Rehabilitation Research and Development Service (Project #B596-RA, Part 3); Liberty Mutual Insurance Company; Patricia Roberts Harris Fellowship

Purpose—The present project approaches the question of postural control from the perspective of nonlinear dynamics. Chaos can be defined as the occurrence of apparently random behavior in a deterministic dynamical system. Both ordered and chaotic states can be obtained in nonlinear systems. On the basis of earlier work carried out at the NeuroMuscular Research Center, it is proposed that the highly irregular and periodic components identified in actual measurements of the motion of the center of pressure are not manifestations of different underlying mechanisms, but represent the output of a deterministic nonlinear dynamical system.

The goal of this work is to introduce the ideas of geometric dynamics into the experimental domain of posturography. Time series of stabilogram data obtained from force platforms can be used to

construct phase portraits (i.e., geometric representations of the behavior of a dynamical system). Qualitative and quantitative information extracted from phase space reconstructions and scalar time series can be compared with studies of canonical nonlinear model systems. This approach can be utilized to test the applicability of a number of possible models of the postural control system and may be useful for quantifying the changes associated with the natural aging process, the progression of a neuromuscular disability or the progression of a rehabilitation program.

Progress—Mathematical techniques and algorithms from dynamical systems theory are currently being developed and implemented at the NeuroMuscular Research Center to study nonlinear phenomena in the behavior of the human postural control system.

[268] Posture and Movement Stability: A Stochastic Approach to Posturography

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Sponsor: *VA Rehabilitation Research and Development Service (Project #B596-RA, Part 4); Liberty Mutual Insurance Company; Patricia Roberts Harris Fellowship*

Purpose—The task of maintaining an upright posture involves a complex sensorimotor control system. Even when an individual attempts to stand still, the center of gravity of his or her body and the center of pressure (COP) under his or her feet move relative to a global laboratory coordinate system. A stabilogram is a plot of the time-varying coordinates of the COP, as measured by a force platform. Previous work at the NeuroMuscular Research Center has suggested that a stabilogram generated by a normal subject in quiet standing consists of two components: a random component similar to the trajectory of a random walker, and a periodic cyclic component. To test this idea, we have undertaken a number of theoretical and experimental investigations.

Methodology—Time series of COP coordinate data were collected for 10 healthy subjects—five females and five males—from 20 to 31 years of age. The

COP trajectories were studied as one-dimensional (mediolateral and anteroposterior, respectively) and two-dimensional random walks.

Preliminary Results—Preliminary data analysis demonstrated that intra-subject differences were of the same magnitude as inter-subject differences for the currently used experimental protocols. Computer simulations of the trajectory of a particle subjected to a randomly fluctuating force and/or a periodic force had a remarkably similar appearance to experimentally measured stabilograms.

Implications—The simulations suggested that a random mechanism can produce behavior which appears to be periodic on certain time scales. It is unclear whether analytical methods from statistical mechanics can be utilized to describe consistently the degree of randomness that characterizes the postural control capacity of an individual subject.

[269] Posture and Movement Stability: Modeling a Simple Chaotic System

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Sponsor: *VA Rehabilitation Research and Development Service (Project #B596-RA, Part 5); Liberty Mutual Insurance Company; Patricia Roberts Harris Fellowship*

Purpose—Chaos is a term used to denote the apparently stochastic time-varying behavior of a noise-free, deterministic system. Since the time-history of a chaotic system has a sensitive dependence on initial conditions, its long-term state is unpredictable from a practical standpoint. It has been demonstrated that very simple deterministic physical and mathematical systems can exhibit chaotic behavior. One such system is a 2-degree-of-freedom pendulum made up of a rigid rod with a magnet attached to its distal endpoint which is suspended above a symmetrical, planar arrangement

of attractive and repulsive magnets. The pendulum will follow periodic, quasi-periodic and chaotic trajectories, depending upon the initial position and velocity of the swinging magnet and the configuration of the stationary magnets. The equations describing such a system formed the basis of an interactive computer program, which was implemented on a desktop computer at the NeuroMuscular Research Center.

Progress/Methodology—The program is designed such that the parameters and initial conditions of

the modeled system can be altered by the user. The software also enables users to simulate the effects of white noise and various forms of damping (i.e., positive or negative) on the motion of the swinging magnet. Time series generated by the model are currently being used to test a number of numerical algorithms adapted from the fields of signal processing and dynamical systems theory.

Future Plans/Implications—The present computer model has potential pedagogical value in the undergraduate curriculum since it can be utilized to illustrate the general concepts underlying chaos and nonlinear dynamics. Moreover, by studying simple, nonlinear deterministic equations and systems, we hope to gain additional insight into the behavior of various neuromuscular systems, including the human postural control system.

[270] Skeletal Muscle Architectural Design: Implications for Tendon Transfer

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Sponsor: *American Society for Surgery of the Hand*

Purpose—The purpose of this project was to elucidate the design of the various human forearm muscles. The goal was to better understand which muscles would provide appropriate function for other muscles secondary to surgical tendon transfer.

Methodology/Results—This study was based on the fact that skeletal muscle architecture dramatically influences function. The detailed fiber arrangement from 255 muscles taken from 27 cadaveric specimens was measured and submitted for discriminant analysis for determination of the structural factors which most strongly differed between functional groups. It was found that the five most important discriminators for all muscles were: physiological cross-sectional area, fiber length, fiber length to muscle length ratio, mass, and muscle length. These five discriminating parameters were then used to create an "architectural difference index" which represented the overall differences between muscles

in a single value. Then, various tendon transfer procedures were evaluated based on architectural difference indices.

Future Plans—Future studies are designed to evaluate the efficacy of various surgical treatments based on architectural difference indices.

Recent Publications Resulting from This Research

- Architecture of Selected Wrist Flexor and Extensor Muscles. Lieber RL, Fazeli BM, Botte MJ, *J Hand Surg* 15:244-250, 1990.
- Pronator Teres and Brachioradialis: Two Muscles of the Same Size But Very Different Designs. Lieber RL, Fazeli BM, Botte MJ, in *Transactions of the 37th Orthopedic Research Society* 37:661, 1991.
- Architecture of Selected Muscles of the Arm and Forearm: Anatomy and Implications for Tendon Transfer. Lieber RL, Jacobson MD, Fazeli BM, Abrams RA, Botte MJ, *J Hand Surg* (in press).
- Quantitative Method for Comparison of Skeletal Muscle Architectural Properties. Lieber RL, Brown CG, *J Biomech* (in press).

[271] Mechanism of Torque Generation in the Frog Hindlimb

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Sponsor: *National Institute of Arthritis and Musculoskeletal and Skin Diseases, National Institutes of Health*

Purpose—The purpose of this project was to determine the relative influence of muscle intrinsic properties, moment arm, and tendon compliance on

the nature of the torque profile on the frog hindlimb.

Methodology—Muscle sarcomere length, moment arm and tendon strain were measured in the frog hindlimb (*Rana pipiens*) at 10-degree increments over the hip joint range from 130 to 150 degrees. Hip torque was also directly measured over the same range.

Results—The relationship between sarcomere length and joint angle were as previously measured. We found that in this system, moment arms dominated the shape of the torque profile, accounting for over 75% of the experimental variability. Muscle force accounted for almost 20% of the variability, and tendon compliance for less than 5% of the variability. These data suggest that in the frog muscle-joint

system, since muscle fiber length is relatively long compared to the moment arm, moment arm will dominate the nature of the torque profile. Future studies are underway to determine these types of relationships in muscle-joint systems.

Recent Publications Resulting from This Research

- Interaction Between Semitendinosus Muscle and Knee and Hip Joints During Torque Production in the Frog Hindlimb. Mai MT, Lieber RL, *J Biomech* 23:271-279, 1990.
- Sarcomere Length, Hip Joint Moment Arm and Muscle Force Used as Torque Predictors in the Frog Hindlimb. Lieber RL, Shoemaker SD, Green AM, *Physiologist* 33:A120, 1990.
- Measurement and Prediction of Hip Joint Moment in the Frog Hindlimb. Shoemaker SD, Green AM, Lieber RL, in *Transactions of the 37th Orthopedic Research Society*, 37:585, 1991.

[272] Change in Tendon Properties During Muscle Activation

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Sponsor: *National Institute of Arthritis and Musculoskeletal and Skin Diseases, National Institutes of Health*

Purpose—The purpose of this study was to understand the relationship between tendon and muscle properties during active contraction.

Results—It was found that during active contraction, tendon and muscle tendon junction regions were much stiffer than those measured during slow passive loading. This was expected, based on the well-known viscoelastic properties of tendon. However, what was not expected was that the properties of the muscle tendon junction actually changed during active contraction. These results suggest that the intimate relationship between muscle fibers and tendon may actually cause a change in aponeurosis

properties which occurred during muscle activation.

Recent Publications Resulting from This Research

- Frog Semitendinosus Tendon Properties During Passive Stretch and Active Muscle Contraction. Leonard ME, Trestik CL, Lieber RL, in *Transactions of the 37th Orthopedic Research Society* 37:612, 1991.
- Physiological Implications of Tendon Compliance. Trestik CL, Leonard ME, Lieber RL, in *Transactions of the 37th Orthopedic Research Society* 37:133, 1991.
- Frog Semitendinosus Tendon Load-Strain and Stress-Strain Properties During Passive Loading. Lieber RL, Leonard ME, Brown CG, Trestik CL, *Am J Physiol* (in press).
- Model of Muscle-Tendon Interaction During Frog Semitendinosus Fixed-End Contractions. Lieber RL, Brown CG, Trestik CL, *J Biomech* (in press).

[273] Muscle Fiber Damage Due to Eccentric Contractions

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Purpose—The purpose of the project was to determine the mechanism of damage in muscle fibers from the rabbit tibialis anterior. Muscles were cyclically stretched 25% of their fiber length at two

different times during the contractile cycle. In this way, muscle stress was varied between treatment groups, but muscle strain and strain rate were exactly the same.

Results—In spite of the dramatically different stresses experienced by the two different groups, skeletal muscle force following eccentric contraction-induced injury dropped to the same extent in both treatment groups ($p > 0.4$). These data suggest that muscle fiber damage is due primarily to the magnitude of the length change during the eccentric contraction rather than the absolute stress reached during the contraction.

Recent Publications Resulting from This Research

- Immunohistochemical Identification of Cytoskeletal Damage in Muscle Cells Subjected to Eccentric Exercise. Lieber RL, Friden JO, in Transactions of the 36th Orthopedic Research Society 36:542, 1990.
- Damage of the Rabbit Tibialis Anterior Induced by Eccentric Contractions of Twenty-five Percent Strain. Lieber RL, Friden JO, McKee-Woodburn TG, J Appl Physiol 70:2498-2507, 1991.
- The Structural and Mechanical Basis of Exercise-induced Muscle Injury. Friden JO, Lieber RL, Med Sci Sport Exerc (in press).

[274] Human Muscle Mechanics and the Distribution-Moment Model

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Sponsor: National Science Foundation

Purpose—The objective of this research is to develop a previously established mathematical model of skeletal muscle, called the Distribution-Moment (DM) model, and to adapt it to human muscles. The major tasks to be accomplished are an elaboration of the model to account for some metabolic effects, including aerobic and anaerobic recovery during and after contraction (in progress), and simulations of muscle mechanics and concurrent electromyographic (EMG) activity (to be done). It is expected that the product of this work will be an improved representation of the muscle actuator for applications in quantitative studies of human movement and neural prostheses employing functional neuromuscular stimulation (FNS).

Progress/Methodology—The DM model of muscle is based directly on the cross-bridge theory of contraction introduced by A.F. Huxley in 1957. This basic theory, with elaborations, is currently widely accepted within the muscle biophysics community. The DM model provides simplified equations for the direct calculation of the *moments* of the actin-myosin *bond-distribution function*: these moments have macroscopic interpretations as muscle *stiffness*, *force*, and *elastic energy*. The development of the theory is described in the Publications Resulting from This Research section.

Prior to the current project, the DM model had

been developed to account for contraction dynamics (i.e., actin-myosin interactions) and calcium-mediated activation dynamics (i.e., electrical pulse stimulation). Recently, the model has been enhanced to permit the prediction of short-term energetics: chemical energy release and heat production rates. In the first phase of this project, the DM model has been enhanced further to permit the prediction of aerobic and anaerobic recovery, and the interaction of metabolites with contraction dynamics. This has permitted, among other things, the simulation of one contributing factor in fatigue: the decrease in contractile force during continued stimulation resulting from the accumulation of inorganic phosphate.

Future Plans/Implications—Future plans include calculations for ensembles of muscle fibers to predict simultaneously the mechanical, energetic, metabolic, and electrical responses of whole muscle. Each fiber will be represented by a DM model and driven by trains of stimulating pulses, and the electrical activity will be estimated via volume-conductor theory. Through such simulation it is hoped to identify principles which relate the surface or intramuscular electromyogram to mechanical activity (under both isometric and non-isometric conditions), and also possibly to energetic factors (e.g., heat production) and metabolic factors (e.g., lactate production, oxygen consumption).

Recent Publications Resulting from This Research

Chemical Energy Release and Heat Production in Skeletal Muscle: A Distribution-Moment Model. Ma S, Zahalak GI, in *Proceedings of the First World Congress of Biomechanics*, 11:182, 1990.

Modelling Muscle Mechanics (and Energetics). Zahalak GI, in *Multiple Muscle Systems: Biomechanics and Movement Organization*, J.M. Winters, S.L.-Y. Woo (Eds.), Chapter 1. Berlin: Springer-Verlag, 1990.

Muscle Activation and Contraction: Constitutive Relations Based Directly on Cross-Bridge Kinetics. Zahalak GI, Ma S, *J Biomech Eng* 112:52-62, 1990.

A Distribution-Moment Model of Energetics in Skeletal Muscle. Ma S, Zahalak GI, *J Biomech* 24(1):21-35, 1991.

An Overview of Muscle Modelling. Zahalak GI, in *Neural Prostheses: Replacing Motor Function After Disease or Disability*, R.B. Stein, P.H. Peckham, D.P. Popovic (Eds.). New York: Oxford University Press, Inc. (in press).

[275] Skeletal Muscle Reaction to Immobilization

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Sponsor: *Netherlands Organization for Research, Foundation for Biological Sciences*

Purpose—The purpose of this study was to predict the reaction of human skeletal muscle to immobilization regarding length, duration of immobilization period, and position of the limbs.

Progress—A muscle model, relating the architecture of the skeletal muscle to its functional capacity, was formulated and experimentally determined on rat calf muscle and various others. The model was applied to human calf muscle using morphological data of human cadavers. The model was also applied in a description of muscular growth. It is now being used in analyzing the effects of various periods of immobilization in different positions, leading to differing muscle lengths.

The work is part of a program on “form, function, and coordination of skeletal muscles,” in which we have tried to relate the results of experimental analysis of animal muscular function to real life human movements in vertical jumping and running.

Results—Effects were studied of 4- to 6-weeks immobilization of calf muscles in growing rats. Soleus muscle atrophied and lost sarcomeres in shortened immobilization; gastrocnemius muscle only atrophied. In comparing experimental muscle data with controls, contralateral muscles should not be used in growing animals. Contralateral muscles are also subject to alteration due to a combination of arrested growth and real atrophy. Muscles of

control animals of the same age are better controls.

In pennated muscles such as the gastrocnemius, the influence of immobilization on the muscle mass, fibers, and aponeurosis could be analyzed. Angles between these components did not alter significantly such that the atrophied muscles were of the same architecture as their controls.

Future Plans/Implications—Comparison will be made of normal and experimentally altered muscles during various states of contraction. The interrelationships of muscular and connective tissue in growing and functioning muscle will be studied in more detail.

Recent Publications Resulting from This Research

Architecture and Elastic Properties of the Series Elastic Element of Muscle-Tendon Complex. Ettema GJC, Huijing PA, in *Multiple Muscle Systems: Biomechanics and Movement Organization*, 57-68, J.M. Winters, S.L.-Y. Woo (Eds.), New York: Springer-Verlag, 1990.

Effects of Growth on Architecture and Functional Characteristics of Adult Rat Gastrocnemius Muscle. Heslinga JW, Huijing PA, *J Morphol* 206:119-132, 1990.

Mechanical Output About the Ankle Joint in Isokinetic Plantar Flexion and Jumping. Bobbert MF, van Ingen Schenau GJ, *Med Sci Sports Exerc* 22:660-668, 1990.

Series Elastic Properties and Architecture of Skeletal Muscle in Isometric and Dynamic Contractions. Ettema GJC, PhD diss., Vrije Universiteit, Amsterdam, 1990.

The Force-Length Relationship of a Muscle Tendon Complex: Experimental Results and Model Calculations. Bobbert MF, Ettema GJC, Huijing PA, *Eur J Appl Physiol* 61:323-329, 1990.

[276] Coordination of Muscles in Gait

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Sponsor: *Netherlands Organization for Research, Foundation of Biophysics*

Purpose—The coordination of lower limb muscles has been studied when one is jumping, bicycling, and walking. Rules for the function of biarticular leg muscles in these movements have been formulated and tested.

Methodology—Inverse dynamic modeling of running and walking in combination with simulation of various forms of jumping are used. Modeling data are acquired with high-speed film and with 1991 VICON systems, force platform, and SMG. For simulation, a SPACAR model that applies finite element analytic instruments to problems of dynamics is used.

Progress/Results—Biarticular muscles play a unique role in transporting rotational energy from proximal to distal segments when a person jumps up and down. The muscles contribute to the mechanical goal of the movement—maximizing effective power at take-off. They compensate for the diminishing contribution to translation of the body's center of gravity by extension (rotation) of lower limb segments.

Timing of the activation of these muscles is important, as is the fact that they co-contract with their antagonists. In bicycling, it appeared essential that such co-contractions were instrumental in producing thrust, as well as direction of movement in the extending limb.

We have tried to validate these concepts in

human walking and running by experimenting and modeling. In gait, biarticular hamstring and rectus femoris muscles are active in early stance. They co-contract with monarticular hip and knee extensors, and tune hip and knee movements while the leg is shortening and lengthening (knee flexion), regulating the level of potential energy. The results are now analyzed and will be compared with muscular function in movements of the arm. In the latter, the situation is more complex; 3-D analysis is necessary.

Future Plans—Jumping up and down, and the timing and geometrical properties of the system will be analyzed by modeling. A model (SPACAR) has been developed that applies finite element analytic instruments to problems of dynamics. Force platform, movement, and electromyographic registration of long jumps, running, arm movements, and walking will be analyzed using this model. The same techniques are used in simulation.

Recent Publications Resulting from This Research

On the Action of Biarticular Muscles: A Review. Van Ingen Schenau GJ, Neth J, *Zool* 40:521-543, 1990.

The Activation of Mono- and Bi-Articular Muscles in Multijoint Movements. Gielen S, in *Multiple Muscle Systems: Biomechanics and Movement Organization*, 302-311, J. Winters, S.L.-Y. Woo (Eds.). New York: Springer-Verlag, 1990.

The Unique Action of Bi-Articular Muscles in Leg Extensions. Van Ingen Schenau GJ, Bobbert MF, Van Soest AJ, in *Multiple Muscle Systems: Biomechanics and Movement Organization*, 639-652, J. Winters, S.L.-Y. Woo (Eds.). New York: Springer-Verlag, 1990.

[277] Use of EMG Power Spectral Analysis to Evaluate a Low Back Pain Exercise Treatment

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Purpose—It has been suggested that electromyographic power spectrum analysis (EMG PSA)

may be an objective, noninvasive treatment outcome evaluation measure for low back pain (LBP) thera-

pies. This suggestion is congruent with the current view that much idiopathic LBP is due to muscular deficiencies, particularly in endurance capacity. Exercise-based therapies for LBP seek to redress these deficiencies through inducing counteradaptations. The sensitivity of EMG PSA to changes in paraspinal muscle functioning has, however, not yet been tested. The objective of this study was to determine the sensitivity of EMG PSA to muscle adaptations in LBP patients who participate in a therapeutic exercise program.

Methodology—EMG activity of the multifidus and iliocostalis muscles was recorded during a constant force contraction in 15 LBP patients (7 males, 8 females). The recordings were taken before and after a 10-week period during which subjects attended two classes per week (20-min. education; 40-min. extension/flexion strengthening exercises and stretching). Additional pre-post assessments included physical fitness and psychosocial measures. Initial median frequency estimates (MF) and fatigue-related parameters (fatigue) of the EMG signal were

determined, and analyzed via a correlated *t*-test.

Preliminary Results—The primary findings were: (a) reduction in localized muscle fatigue for both multifidus (56% reduction; $p < 0.03$) and iliocostalis (33% reduction; $p < 0.04$, muscles; (b) increases in MF value for the multifidus muscle ($x = 6.58$ Hz; $p < 0.03$); and unchanged MF for the iliocostalis muscle ($x = 0.04$ Hz; $p < 0.98$). These EMG changes were accompanied by improvements in physical fitness and psychosocial parameters.

Future Plans/Implications—The findings suggest that EMG PSA of the paraspinal muscles is sensitive to muscular adaptations to back exercises, and present a valid and useful treatment outcome evaluation measure.

Recent Publications Resulting from This Research

Sensitivity of EMG Power Spectral Analysis to the Effects of an Exercise Program for Low Back Pain. Thompson DA, Biedermann HJ, Stevenson JM, Arch Phys Med Rehabil (in press).

[278] EMG Power Spectral Analysis of the Lower Back Muscles: Long-Term Test-Retest Reliability

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Sponsor: Physicians' Services, Inc. Foundation; Ontario Ministry of Health

Purpose—While the value of electromyographic power spectral analysis (EMG PSA) in differentiating patients from controls has been supported, it has not been tested yet as a therapeutic outcome measure. As a prerequisite to such testing, the long-term reliability of paraspinal EMG PSA must be established, since a high degree of stability between repeated measurements is needed when evaluating treatment-induced changes. Previous studies have shown that parameters of the EMG PSA of back muscles can be recorded reliably over a 5-day test-retest interval. The objective of the present study was to determine test-retest reliability over a 3-month period.

Methodology—EMG activity of the multifidus and iliocostalis muscles was recorded during a constant

force contraction in 16 sedentary women. Fitness testing at pre-post assessments showed no change in the physical condition of the subjects over the 3-month interval. Initial median frequency estimates (MF) and a fatigue-related parameter (fatigue) of the EMG signal were determined, and analyzed via Pearson product-moment correlation.

Preliminary Results—The test-retest correlation coefficients, which were averaged over the multifidus and iliocostalis muscles, were 0.97 for the MF, and 0.75 for the fatigue parameter.

Implications—For clinical application and research purposes, the EMG PSA procedure was shown to be highly reliable over a 3-month period for the MF and fatigue parameters of the paraspinal muscles.

This finding allows the method to be evaluated with regard to its validity as a treatment outcome measure.

Recent Publications Resulting from This Research

Median Frequency Estimates of Paraspinal Muscles: Reliability

Analysis. Biedermann HJ, Shanks GL, Inglis J, Electromyogr Clin Neurophysiol 30:83-88, 1990.
Long-Term Test-Retest Reliability of EMG Power Spectral Analysis of the Paraspinal Muscles. Thompson DA, Biedermann HJ, Arch Phys Med Rehabil (in press).

[279] Localized Body Fat: A Confound for EMG RMS Measures of Muscle Activity

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Purpose—The relationship between surface recorded paraspinal electromyographic (EMG) activity and chronic back and neck pain has received substantial investigation, with numerous studies employing EMG amplitude measures (RMS) to assess patient status and treatment efficacy. Comprehensive normative databases have been published which have been accumulated into tables for many different muscle sites of the back and corresponding muscle tension levels to up to 1/100 μ V accuracy. However, the value of EMG RMS measurements and normative data has been questioned previously on the basis of experimental design considerations and technical concerns. The purpose of the present investigation was to study the specific effect of body fat at the EMG surface recording site on the RMS parameter.

Methodology—EMG activity was recorded in 20 normal controls during a constant force contraction. Test-retest analysis of this procedure yielded reliability coefficients of 0.9. Localized skinfold measures were taken at four recording sites and entered as independent variables in a linear regression with EMG activity (RMS) as the dependent measure.

Results—The findings suggest that between 52% and 81% of the intersubject variance in paraspinal EMG RMS can be related to variation in skinfold thickness.

Implications—These observations support the view that EMG RMS measures and the corresponding reference tables should be treated with caution when used to assess patient status and treatment outcome.

[280] Sensitivity of Electromyographic Spectrum Analysis of Paraspinal Muscles to Changes Following Physical Training

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Purpose—It has been suggested that electromyographic power spectrum analysis (EMG PSA) of the paraspinal muscles has two major clinical purposes in the area of low back pain: 1) patient status evaluation; and, 2) treatment-outcome evaluation. While the usefulness of EMG PSA in differentiating back pain patients from controls has been demonstrated, no information is available on the sensitivity of this methodology to muscle adaptations resulting

from physical therapy (e.g., increased oxygenation, metabolic capacity, cross-sectional muscle fiber area). We are investigating the relationship between changes in fitness parameters (related to such adaptations) and changes in EMG PSA.

Progress—Previously sedentary healthy women have undergone fitness tests (which determine aerobic capacity, strength, flexibility, body composition),

and EMG PSA of the iliocostalis and multifidus muscles, before and after a 12-week period during which they volunteered to attend 3-5 fitness classes per week. These data are being compared to those of control subjects who remained sedentary. Statistical analyses are underway to determine the relative

power of the fitness and EMG PSA measures to detect changes induced by physical training, and the relationship between these adaptations and the EMG PSA parameters (e.g., initial median frequency, fatigue rate, recovery).

B. Ligaments and Tendons

[281] Laser Biostimulation of Healing Tendons: Effects of Treatment Parameters

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Sponsor: VA Rehabilitation Research and Development Service (Project #A534-RA)

Purpose—Our previous reports indicate that He:Ne laser photostimulation promotes the healing process of experimentally tenotomized rabbit calcaneal tendons. To advance this line of investigation, we compared the relative effects of He:Ne and Ga:As laser photostimulation on healing tendons.

Methodology/Results—The right calcaneal tendons of 20 rabbits were tenotomized, repaired, and immobilized in plaster casts. Beginning one day after surgery, the repaired tendons of 13 rabbits were exposed to daily doses of either 1 J cm⁻² He:Ne laser [N=6] or 1 J cm⁻² Ga:As laser [N=7]. The remaining seven tendons served as nontreated controls. On the 14th postoperative day, the tendons were excised and tested on an Instron device for differences in tensile strength, tensile stress, and energy absorption capacity. Analysis of covariance (ANCOVA) showed that the mean tensile strength of He:Ne and Ga:As laser photostimulated tendons, 80.17 ± 13.60 and 94.71 ± 12.27 N respectively, were significantly different from control values, 56.4 ± 4.05 N. *Post hoc* tests revealed that both He:Ne and Ga:As laser photostimulation significantly increased the tensile strength of the tendons over controls. Correspondingly, the mean tensile stress of

He:Ne and Ga:As photostimulated tendons, 233.78 ± 31.58 N cm⁻² for He:Ne laser-treated group and 251.61 ± 34.35 N cm⁻² for Ga:As laser-treated group, were significantly higher than the mean control value, 153.56 ± 11.63 N cm⁻². Although the mean tensile strength and tensile stress of laser-treated tendons were higher than those of controls, no statistically significant differences were found in the mean tensile strength and mean tensile stress of both groups of treated tendons. Moreover, no statistically significant differences were found in the energy absorption capacity of laser-treated and control tendons.

Implications—These findings indicate that 1 J cm⁻² He:Ne or 1 J cm⁻² Ga:As laser can augment the healing strength of experimentally tenotomized rabbit calcaneal tendons and that at 1.0 J cm⁻² the same biomechanical effects are produced by both lasers.

Recent Publications Resulting from This Research

Morphometrics of Collagen Fibril Populations in He-Ne Laser Photostimulated Tendons. Enwemeka CS, Rodriguez O, Gall NG, Walsh NE, *J Clin Laser Med Surg* 8:151-156, 1990.

Laser Photostimulation in the United States. Enwemeka CS, in: *Progress in Laser Therapy*. T. Oshiro, R.G. Calderhead (Eds). New York: John Wiley & Sons, 1991.

[282] Structural and Functional Properties of Normal and Healing Ligaments: Part I

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Sponsor: VA Rehabilitation Research and Development Service (Project #A188-4RA)

Purpose—We have developed a new injury model to study medial collateral ligament (MCL) healing in the rabbit. Although many experimental animal models have been used to examine MCL healing, few have included a concomitant injury to the ligament insertions to bone as observed clinically. Using a combined injury model, long-term healing was evaluated following conservative treatment or primary repair of the MCL.

Methodology—The left MCL of each skeletally mature New Zealand White rabbit was surgically exposed and a 2.5 mm diameter stainless steel rod was passed transversely beneath the ligament at the joint line. A small notch was made on each side of the MCL at the level of the rod. The ligament was ruptured in tension by pulling on the rod, creating a "mop-end" midsubstance tear. In half the animals, the torn ligament ends were surgically repaired, while those of the remaining animals were manually approximated. At 6, 12, and 52 weeks postoperatively, one third of the animals in each group were sacrificed and healing of the MCL was evaluated by comparing the V-V knee rotation, the structural properties of the femur-MCL-tibia complex (FMTC), and the mechanical properties of the MCL substance.

Results—No significant differences were seen in the V-V rotations or the tensile properties between the repaired and nonrepaired groups at either 6, 12, or 52 weeks, suggesting that in a model that combines MCL substance and insertion site injury, surgical repair of the MCL and conservative treatment yield similar results. At both 6 and 12 weeks, the V-V rotations of the repaired and nonrepaired knee and structural properties of the repaired and nonrepaired FMTCs (ultimate load, ultimate deformation energy absorbed, and stiffness) were significantly different from those of the contralateral sham-operated knees ($p < 0.001$ in all cases). However, by 52 weeks, the V-V knee rotation and linear stiffness of the

experimental FMTCs were not significantly different from the sham values ($p > 0.1$ in all cases). There was a significant effect of healing time ($p < 0.01$) on these properties. At 12 and 52 weeks postoperatively, all experimental specimens failed in the ligament substance and the tensile strength and ultimate strain of both the repaired and nonrepaired specimens were significantly less than that of the shams ($p < 0.01$ in all cases).

Future Plans/Implications—The rates of recovery between the ligament substance and the insertion sites were found to be asynchronous, as there was a progressive change in failure mode from tibial avulsion at 6 weeks to mid-substance at 52 weeks. The strength of the tibial insertion site increased during the time course of healing, while the ligament substance showed little change after the first 12 weeks. A lack of complete recovery of the mechanical properties of the MCL was observed. However, increases in MCL cross-sectional area helped the FMTC to achieve structural properties near to those of the sham control. This suggests that this is a useful model of clinical injury, and therefore, is suitable for the long-term study of grade III MCL injury.

Recent Publications Resulting from This Research

Effects of Surgical Treatment and Immobilization on the Healing of the Medial Collateral Ligament: A Long-term Multidisciplinary Study. Inoue M, et al., *Conn Tiss Res* 20:1-14, 1990.

Long-term Healing of the Femur-Medial Collateral Ligament-Tibia Complex (FMTC). Weiss JA, et al., *Transactions of the First World Congress of Biomechanics*, La Jolla, CA, 11:292, 1990.

The Use of a Laser Micrometer System to Determine the Cross-Sectional Shape and Area of Ligaments: A Comparative Study with Two Existing Methods. Woo SL-Y, et al., *J Biomech Eng*, 12:426-431, 1990.

Evaluation of a New Injury Model to Study Medial Collateral Ligament Healing: Primary Repair vs. Conservative Treatment. Weiss JA, et al., *J Orthop Res* 9:516-528, 1991.

Healing of Ruptured MCL and Its Insertion Sites. Woo SL-Y, Ohland KJ, Weiss JA, AOSSM/JOSSM Trans-Pacific Meeting, Kauai, HI, 74-75, 1991.

Long-Term Healing of the Medial Collateral Ligament (MCL) and Its Insertion Sites. Ohland KJ, et al., in Transactions of the 37th Annual Orthopedic Research Society, Anaheim, CA, 16(1):158, 1991.

[283] Structural and Functional Properties of Normal and Healing Ligaments: Part II

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Sponsor: VA Rehabilitation Research and Development Service (Project #A188-4RA)

Purpose—The objectives of this study are to compare the medial collateral ligament (MCL) healing processes following injury by surgical transection or by rupture. Studying the two injury models will help to clarify whether changes in the ligament insertion sites following rupture are attributable to a lack of stress during healing or to damage at the time of injury.

Methodology—The MCL of the left knee of skeletally mature New Zealand White rabbits was transected with a scalpel blade (Group I) or ruptured by pulling medially on a 2.5 mm diameter rod passed beneath the ligament (Group II). At 6 weeks postoperatively, six animals in each group were euthanized and the knees were evaluated. The healing of the MCL was evaluated by comparing the V-V knee rotation, the structural properties of the femur-MCL-tibia complex (FMTC), and the mechanical properties of the MCL substance.

Results—The V-V knee rotations of the Group I and II experimentals were significantly (1.7 times) higher than the contralateral uninjured controls for each

group ($p < 0.05$). No significant differences in structural properties were observed between the two experimental groups ($p > 0.1$). Following 6 weeks of healing, all Group I FMTCs failed in the ligament substance, while all Group II FMTCs failed by tibial avulsion.

Future Plans/Implications—Comparison of the V-V knee rotations and the structural properties of the FMTC between Groups I and II indicate that the healing response is similar. However, the involvement of damage to the tibial insertion site in Group II is clearly illustrated by the failure modes of the FMTCs. The differences in the results suggest that rupturing the bone-ligament complex may represent a more suitable model for future examination of effects of factors on treatment and rehabilitation following MCL injury.

Recent Publications Resulting from This Research

Surgical Transection vs. Rupture of the Medial Collateral Ligament: Differences in the Healing Process. Ohland KJ, et al., in Transactions of the 38th Annual Orthopedic Research Society, 17, 1991.

[284] Structural and Functional Properties of Normal and Healing Ligaments: Part III

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Purpose—Complete disruption of the medial collateral ligament (MCL) often occurs together with

rupture of the anterior cruciate ligament (ACL) and damage to the medial meniscus—the so called

"triad" injury. Using our recently developed model for MCL injury, which included damage of the MCL substance as well as its insertions to bone, we examined MCL healing following a triad injury.

Methodology—The MCL of the left knee of skeletally mature New Zealand White rabbits was ruptured at the joint line by pulling medially on a 2.5 mm diameter rod passed beneath the ligament. In half the animals, the ACL was then surgically transected and the inner rim (~50%) of the medial meniscus was excised. At 6 and 12 weeks postoperatively, half the animals in each group (isolated MCL rupture and triad injury) were sacrificed, and healing of the MCL was evaluated by comparing the V-V knee rotation, the structural properties of the femur-MCL-tibia complex (FMTC), and the mechanical properties of the MCL substance. The V-V knee rotations of an additional six knees were measured intact and successively following isolated MCL rupture and triad injury.

Results—The animals with a triad injury experienced substantial joint degeneration by 6 weeks. V-V rotations were nearly three times higher for the triad knees than for those with isolated MCL rupture ($p < 0.001$) and remained elevated with time. The ultimate load of the FMTCs of the triad injured knees improved with time ($p < 0.05$), but were only 55% of those with isolated MCL rupture ($p < 0.05$). The modulus of the healing tissue from the triad

injured knees was less than half of that of the tissue from the isolated MCL ruptured knees ($p < 0.05$).

Future Plans/Implications—This study demonstrates the deleterious effects of an untreated triad injury on the healing potential of the MCL substance and its insertions. The biomechanical properties of the FMTC and MCL substance imply that the MCL forms a much larger structure following triad injury in an attempt to compensate for its inferior mechanical properties. Additionally it was found that after ACL reconstruction, the V-V rotation of the triad injured knees could be restored, suggesting that the healing of the MCL may be enhanced by restoring ACL function. We plan to evaluate MCL healing at 6, 12, and 52 weeks following triad injury with ACL reconstruction.

Recent Publications Resulting from This Research

- Biomechanics and Morphology of the Medial Collateral and Anterior Cruciate Ligaments. Woo SL-Y, Weiss JA, MacKenna DA, First World Congress of Biomechanics, LaJolla, CA, 11:28, 1990.
- Evaluation of a New Injury Model to Study Medial Collateral Ligament Healing: Primary Repair vs. Conservative Treatment. Weiss JA, et al., J Orthop Res 9:516-528, 1991.
- Healing of Combined Injuries of the Rabbit Medial Collateral Ligament and its Insertions: A Long Term Study on the Effects of Conservative vs. Surgical Treatment. Ohland K, et al., ASME Abstracts, December 1991.
- Healing of the Medial Collateral Ligaments Following a Triad Injury. Anderson DR, et al., 1991 ABME Shuman Applied Mechanics and Biomechanics Conference, Columbus, OH, 120:197-199, 1991.

IX. Neurological and Vascular Disorders

A. General

[285] Comparison of Treatment Programs for Multiple Sclerosis Rehabilitation

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Sponsor: VA Rehabilitation Research and Development Service (Project #B395-RA)

Purpose—The goal of this project is to examine the effectiveness of interdisciplinary team care in comparison with standard neurological care for patients with multiple sclerosis (MS). Our main hypothesis is that coordinated care by experienced practitioners will maximize patient quality of life and may eliminate preventable complications of MS.

Methodology—Patients with definite or probable MS are evaluated at baseline, 6, and 12 months. Study measures include the Minimal Record of Disability for Multiple Sclerosis (MRD), the Sickness Impact Profile (SIP), patient satisfaction with health care, the Campbell Index of Life Satisfaction, and enumeration of VA and non-VA medical expenditures. Patients at the Portland VA Medical Center (VAMC) will continue to receive comprehensive neurological care. Patients at the Denver VAMC will be treated in an interdisciplinary team clinic, managed by a nurse practitioner case manager. The team carries out a comprehensive evaluation of the physical, psychological, and social status of the patient. Realistic care and rehabilitation goals are established; the nurse practitioner ensures that the plans are effectively carried out.

Progress—A total of 163 patients have participated in the study (82 at Denver and 81 at Portland), with 128 patients completing the 12-month follow-up. The patients were 88% male (average age 49 years). Most (67%) had chronic progressive MS with an average duration of 17.7 years. The average Ex-

panded Disability Status Scale (EDSS) scores were 6.1. Overall, the Portland patients have a more severe degree of MS than do the Denver patients (EDSS 5.7 in Denver and 6.4 in Portland, $p=0.01$), and are older (47.2 years in Denver and 51.9 years in Portland, $p=0.012$).

Preliminary Results—We found that the patients had similar rates of hospitalization during a 3-year baseline period (0.29/pt/yr in Denver and 0.32/pt/yr in Portland, $p=0.646$), but interdisciplinary team patients were hospitalized at twice the rate of the Portland patients during the follow-up period (0.69/pt/yr in Denver and 0.35/pt/yr in Portland, $p=0.001$). The bulk of the additional admissions were for inpatient rehabilitation.

At 12 months, the average EDSS score declined at both sites to 5.8 at Denver and 6.9 at Portland with no significant difference in the rate of decline between the two sites. Functional status, as measured by total Incapacity Status Score (ISS), declined at a similar rate at the two sites over the 12-month follow-up. Patient-perceived maximal physical and mental capacity was more likely to be stabilized or improved in the Denver group at 6 and 12 months. Patient satisfaction with health care improved in Denver ($p<0.001$) and declined in Portland ($p=0.041$). These findings show that patients are happy with the medical care they receive under an interdisciplinary team and may experience some functional improvements or stabilization. Further testing of the interdisciplinary team concept for MS patient care is warranted.

Recent Publications Resulting from This Research

Care-Giver Burden in Multiple Sclerosis. Prochazka AV, Mitchell W, Licari P, Clin Res 38:107A, 1990.
 Health Care Costs of Multiple Sclerosis. Bourdette DN, et al., Neurology 40:(S1)276, 1990.
 Predictors of Happiness in Multiple Sclerosis. Prochazka AV, et al., Clin Res 38:741A, 1990.

Evidence That Multidisciplinary Teams are Effective in the Care of Veterans with Multiple Sclerosis. Bourdette D, et al., Neurology 41(S1):353, 1991.

Bladder, Bowel and Sexual Dysfunction in Multiple Sclerosis. Bourdette DN, in Multiple Sclerosis: Current Status of Research and Treatment, R.M. Herndon, F.J. Seil (Eds.), New York: Demos Publications (in press).

[286] Ideomotor Apraxia: Recovery and Treatment

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Sponsor: VA Rehabilitation Research and Development Service (Project #C567-RA)

Purpose—The present work was undertaken because little is known about recovery and treatment of ideomotor apraxia, a disorder of skilled limb movement associated with left cerebral hemisphere brain damage. Disruption of a system that mediates skilled movement may not only affect ability to manipulate objects, as in tool use, but also may affect other forms of skilled movement, such as gesture. Since gesture is an important communicative strategy in the aphasic patient and impairment of praxis is a common concomitant of aphasia, the speech/language pathologist may need to treat ideomotor apraxia in some aphasic patients.

Little is known about the recovery of ideomotor apraxia, thereby restricting the ability of the clinician to make predictions about the evolution of apraxia and the potential for change of behaviors related to apraxia. Recovery information may be important in selecting treatment approaches as well as in predicting the abilities of the patient in activities of daily living.

Methodology—This research program has thus far involved four different ongoing studies investigating gestures and tool use in patients with left hemisphere cerebrovascular accidents (CVA). In the first study, patients are videotaped in their rooms while using tools and gestures during mealtime. To assess the presence of apraxia, patients are also videotaped while performing gestures on command. The videotapes will be analyzed for all patients; comparisons will be made between tool-use in the natural environment and gesture to command in clinical examination. In the second study, patients are videotaped while performing gestures on command

at 7- to 14-days postonset and again at 3-months postonset. Lesions will be plotted from computer tomography (CT) scans obtained for clinical purposes following onset of CVA and lesion characteristics will be compared with improvements in gesture performance over time. In the third study, performance of pantomime to command will be videotaped at 6-weeks, 3-months, and 6-months postonset. The evolution of recovery on this task will be analyzed for all patients, looking specifically for patterns of recovery that might be anticipated in treatment planning. Finally, in select apraxic patients, the fourth study will focus on treatment of gesture and pantomime production by providing patients with verbal instruction and visual modeling of gestures in seven treatment tasks across ten treatment sessions.

Progress—Thus far, 10 left-hemisphere-damaged patients have participated in aspects of this project. However, analysis of data awaits completion of testing of all experimental subjects within each study. Therefore, no results are available for dissemination at this time.

Recent Publications Resulting from This Research

Conduction Apraxia. Ochipa C, Rothi LJG, Heilman KM, J Clin Exp Neuropsychol 12:89, 1990.

Error Type Analysis of Buccofacial and Limb Apraxia. Raade A, Rothi LJG, Heilman KM, J Clin Exp Neuropsychol 12:89, 1990.

Ideomotor Apraxia and Visual Imagery. Maher L, et al., J Clin Exp Neuropsychol 12:89, 1990.

Timing Deficits in Limb Apraxia. Poizner H, et al., J Clin Exp Neuropsychol 12:89, 1990.

Three Dimensional Computer-Graphic Analysis of Apraxia: Neural Representations of Learned Movement. Poizner H, et al., *Brain* 113:85-102, 1990.

Unawareness (Anosognosia) of Apraxic Errors. Rothi LJG, Mack L, Heilman KM, *Neurology* 40:202, 1990.

Ideational Apraxia in Alzheimer's Disease. Ochipa C, Rothi LJG, Heilman KM, *J Clin Exp Neuropsychol* 13:49, 1991.

Selective Deficit of Motor Imagery in Ideomotor Apraxia. Ochipa C, et al., *J Clin Exp Neuropsychol* 13:84, 1991.

[287] Muscular and Cardiorespiratory Fitness in Multiple Sclerosis: A Pilot Study

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Sponsor: VA Rehabilitation Research and Development Service (Project #B90-93AP)

Purpose—The primary goal of this research is to evaluate present stress-testing techniques to enable determination of muscular and cardiorespiratory (aerobic) fitness in persons with varying degrees of physical impairment due to multiple sclerosis (MS). Specific objectives are to: 1) characterize upper and lower extremity isokinetic strength; 2) document aerobic metabolic and cardiorespiratory responses during maximal aerobic exercise utilizing three modes of ergometry; 3) develop a fitness scale to characterize physical work capacity; and, 4) develop guidelines for rehabilitation intervention.

Progress—Currently 10 MS and 10 healthy, matched control (nondisabled) subjects have been screened and are participating in the study. All MS subjects have been neurologically confirmed via examination. Subjects in both groups have been assessed for abnormalities in autonomic cardiovascular reflexes using an automated data collection and analysis program. Evaluation of isokinetic upper and lower extremity strength has been completed on 20 subjects.

Methodology—Neurological evaluation and functional rating was derived from using the Kurtzke Functional Systems Scale and the Expanded Disability Status Scale. Isokinetic muscle performance was measured via a KIN-COM™ isokinetic dynamometer. Autonomic regulation of heart rate (HR) and diastolic blood pressure (DBP) was documented using four noninvasive clinical tests. Maximal aerobic power will be evaluated during discontinuous, progressive intensity protocols using legs, arms, and combined arms/legs cycling. Metabolic and cardiorespiratory responses will be measured via

open-circuit spirometry. ECG and blood pressure will be monitored continuously and at timed intervals, respectively. Core and skin temperature will also be monitored continuously. Pre- and post-exercise blood lactates will be obtained via fingertip puncture.

Preliminary Results—To date, we have documented subject responses to the four noninvasive tests of autonomic cardiovascular regulation of HR and DBP. Of the MS subjects tested, 100% appeared to have *normal* responses of HR on the two tests that challenge parasympathetic response. On the two tests that address sympathetic regulation, 9% showed *abnormal* HR response to standing from supine, and 27% had an *abnormal* DBP response to submaximal sustained isometric contraction. Data from the measurements of isokinetic peak torque during concentric and eccentric muscle contraction of the upper and lower extremity musculature revealed that the experimental subjects were not significantly different from their nondisabled counterparts. In several measurements, the MS group was slightly stronger than the control group. It is believed that these findings may be an artifact of sample selection. The distribution of impairment level among the experimental sample is such that 55% were functionally described as having "normal function with minimal signs" on the Kurtzke Expanded Disability Status Scale. These current isokinetic results are contrary to previous findings from this laboratory when a more disabled MS sample was utilized.

Future Plans/Implications—Having completed the tests of autonomic cardiovascular function and

isokinetic muscle performance, participants will undergo evaluation of maximal aerobic power using the three aforementioned modes of ergometry. From these results, we hope to gain an understanding of the manner in which MS affects normal physiologic responses in the exercise setting. If the most appropriate mode of ergometry can be identified for

evaluating exercise capacity in this population, the potential for improving general health and optimal physical functioning may be possible. The results of this may be an increased level of independence, leading to an enhanced quality of life for persons with MS.

[288] Demonstrating the Efficacy of Memory Training

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Sponsor: VA Rehabilitation Research and Development Service (Project #F471-RA)

Purpose—The purpose of the study is to evaluate two approaches to memory training, one for patients with dense amnesic disorder of the Korsakoff type and the other for persistent memory dysfunction following closed-head injury. The first study consists of design, fabrication, and evaluation of a memory prosthesis that contains information important for activities of daily living. The head injury study consists of the development of computer-based memory training methods that utilize various forms of imagery-based organizational strategies.

Progress/Methodology—The prosthesis is being developed and should be completed and evaluated by the end of the project period. Numerous engineering problems have been solved, and "mock-up" prototypes have been evaluated with patients. Associated research demonstrating that severely amnesic patients can probably be taught to use the device has been completed. Software development has been completed for the head-injury component, and programs are now available for administering our "story method" and "face-name association" procedures. Data are being collected from head-injured subjects. The programs are working smoothly, and

the development phase has essentially been completed. The efficacy evaluation must await completion of data collection.

The methodology includes development of hardware and software materials for memory training, and evaluation of those materials with patients. The latter component is still in progress, but the hardware in the form of the prosthesis is nearing completion of a prototype and the software memory training programs are completed and running on Macintosh computers.

Recent Publications Resulting from This Research

Behavioral Neuropsychology. Goldstein G, in *International Handbook of Behavior Modification and Therapy*, 2nd ed., A.S. Bellack, M. Hersen, A.E. Kazdin (Eds.). New York: Plenum Press, 1990.

Predictors of Memory Training Success in Patients with Closed Head Injury. Malec EA, Goldstein G, McCue M, *Neuropsychology* 5:29-34, 1990.

Stroke. Goldstein G, Starratt C, Malec EA, in *Psychological Aspects of Developmental and Physical Disabilities*, M. Hersen, V. Van Hasselt (Eds.). Newbury Park, CA: Sage Publications Inc., 1990.

Memory Rehabilitation. Goldstein G, in *Head Trauma: Acute Care to Recovery*, C.J. Long, L.K. Ross, M.G. Mutchnick (Eds.). New York: Plenum Press (in press).

[289] Adaptation of Constant-Force Traction Unit for Hand Therapy

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Sponsor: VA Rehabilitation Research and Development Center (Core Funds)

Purpose—A constant-force spring device was developed for applying cervical traction during transport

of acute spinal injury patients. Commercialization of this device has been delayed in part because the

market for this application is too small to interest potential manufacturers. Exercise therapy of the hand and wrist is another application for the device that could enlarge the market. The goal of this proposal is to fabricate and test a set of traction units as replacements for hanging-weight and rubber-band force generating mechanisms in hand therapy.

Methodology—The traction unit has nine constant-force springs on spools turning on a common shaft inside a rectangular housing. It is mounted on trunnion pins extending from the ends parallel to the shaft; the pins snap into slotted blocks, which in the latest design, are movable along a pair of posts. The third-generation traction unit has its springs connected to cables which can be pulled from the housing up to 18 inches; the fourth version has bellows-shielded springs limited to 8 inches of travel. A finger ring is used to extend the cable or spring and attach it to a summing bar, which in turn is connected to the halo or tongs for cervical traction. The springs are connected in pairs, with the center spring being added for increments of 2.8 lb force; two traction units can be mounted for the rare cases in which forces higher than 25 lb are prescribed.

Existing products for hand exercise include the J.A. Preston Hand Table, which has five 1.5 lb weights suspended from pulleys under the tabletop. A cable through each pulley can be pulled straight up through a hole in the tabletop, or it can be pulled horizontally after passing over a second pulley approximately 8 inches above the table. Friction causes ± 0.25 to 0.4 lb variation in force between extending and retracting directions of movement

(this compares to ± 0.1 lb for the third-generation and 0.05 lb for the fourth generation constant-force units).

Progress—Under this pilot project, traction units having spring forces of 0.67, 1.0, 1.4, and 2.5 lb are being fabricated. A vertical post with a sliding bracket holds the traction unit at any angle relative to an arm rest. Replaceable summing bars have been made capable of accepting all nine springs (for wrist flexion/extension and pronation/supination) and only three springs (for finger flexion/extension).

The test population comprises a minimum of 4 and maximum of 30 patients undergoing prescribed hand exercise therapy following incomplete spinal injury, tendon transfer rehabilitation, stroke, or other limb disability. Division of the course of therapy into two sequential parts allows each subject to serve as his/her own control.

Future Plans—The subject's prescribed course of exercise will be divided into two parts, with one-half of the sessions using the Preston table (or similar conventional device) and the other half using the constant-force device (which is done first will be randomly determined). Improvement in standard measures, such as range of motion and flexion/extension torque about the relevant joint, will be determined before and after each half of the treatment; average improvement per session will then be calculated. After the complete course of treatment, subjects will be interviewed by a neutral party to ascertain subjective reactions to the two methods.

[290] Rehabilitation of Neurogenic Communication Disorders in Remote Settings

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Purpose—Patients who suffer neurogenic communication disorders and reside where speech-language pathology services do not exist do not receive appraisal and treatment, or they must travel long distances to receive services. We are exploring the use of computer, video laserdisc, and telephonic

technology to provide services where they do not exist.

Methodology—Patients who suffer a neurogenic communication disorder—aphasia, apraxia of speech, dysarthria, dementia, etc.—are being ap-

praised with a battery of measures in two conditions: traditional face-to-face and computer controlled video laserdisc over the telephone. In addition, aphasic patients who meet selection criteria are assigned to either traditional face-to-face treatment or computer controlled video laserdisc treatment over the telephone, for a 6-month trial.

No significant differences in patient performance on the appraisal measures or clinician diagnosis between conditions would suggest computer be substituted for traditional face-to-face appraisal and diagnosis to serve patients who reside in remote settings. Similarly, no significant difference in improvement between conditions in the aphasia treatment trial would suggest computer-controlled video laserdisc treatment over the telephone could be substituted for traditional face-to-face aphasia treatment to serve patients who reside in remote settings.

Results—Our initial investigation simulated delivery of services in remote settings. The lack of significant differences among conditions prompted the current field test of methods and equipment developed in the simulation study. Currently, an existing Speech Pathology Service in VAMC Martinez is connected

by computer-controlled video laserdisc over the telephone to outpatient clinics where speech pathology services do not exist. Patients are appraised in the laserdisc by telephone condition in the outpatient clinic by clinicians located in VAMC Martinez. Patient performance and clinician diagnosis in the laserdisc by telephone condition will be compared with patient performance and clinician diagnosis in a traditional face-to-face condition. Patients participating in the aphasia treatment trial are treated either by computer-controlled video laserdisc over the telephone in the outpatient clinic by a clinician in VAMC Martinez or with traditional, face-to-face treatment. Study patients continue to be entered in both the appraisal and treatment studies. When sufficient sample size has been collected to provide adequate statistical power, comparisons between conditions will be conducted.

Recent Publications Resulting from This Research

Treatment Aphasic Patients Who Reside in Remote Settings. Wertz RT et al., *Asha* 32:65, 1990.

The Potential for Telephonic and Television Technology for Appraising and Diagnosing Neurogenic Communication Disorders in Remote Settings. Wertz RT et al., *Aphasiology* (in press).

[291] Strength in Postpolio Subjects: A Two-Year Follow-up Study

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Sponsor: *Easter Seal Research Foundation*

Purpose—Our research was designed to determine if either symptomatic (complaining of postpolio syndrome) or asymptomatic postpolio subjects lose muscle strength, endurance, work capacity, or ability to recover strength after activity at a greater rate than do control subjects over a 2-year period of time.

Methodology—We studied 30 symptomatic and 17 asymptomatic postpolio subjects and 31 control subjects. Subjects were seen initially and then at yearly intervals for 2 subsequent years. Peak torque of the quadriceps and hamstrings in the thigh and the biceps humerus muscles was measured with a dynamometer. Endurance testing of the quadriceps was performed isometrically at 40% of maximum

isometric torque until the subject was no longer able to maintain the required level of torque. Work capacity was defined as the product of torque and endurance time. Post-endurance peak torque was measured at regular intervals for 10 minutes after the endurance test. Data were analyzed by means of analysis of variance (ANOVA) and repeated-measures ANOVA.

Results/Implications—Analyses of the initial year's data by ANOVA revealed the following: 1) mean peak torques of quadriceps, hamstrings, and biceps were significantly ($p < 0.05$) less in the symptomatic postpolio group than in the other two groups (165 vs 145 vs 99 newton-meters for the quadriceps; 83 vs 77 vs 56 newton-meters for the hamstrings; and 54 vs

51 vs 39 newton-meters for the biceps for the control, asymptomatic, and symptomatic groups, respectively); 2) endurance time was not significantly ($p > 0.05$) different among the three groups (115 vs 119 vs 112 seconds for control, asymptomatic, and symptomatic groups, respectively); 3) work capacity was significantly ($p < 0.05$) less in the symptomatic group than the other two groups (9,257 vs 7,618 vs 4,303 newton-meter-seconds for control, asymptomatic, and symptomatic subjects, respectively); and, 4) relative recovery of strength in the quadriceps was significantly ($p < 0.05$) less at 30 seconds post-endurance-test in the symptomatic group as compared to the other two groups (104 vs 100 vs 87% for control, asymptomatic, and symptomatic groups, respectively). Repeated measures ANOVA revealed no loss of strength (in any of the three muscle groups tested), endurance time, work capacity, or ability to recover strength after fatiguing activity within or among the three groups tested. Thus, symptomatic postpolio subjects have been found to have less strength and capacity to perform work and recover strength less readily than asymptomatic postpolio or control subjects. However, over a 2-year interval of time, no significant loss of strength, work capacity, or recovery ability

was found in the symptomatic subjects. Further study is being conducted on these subjects.

Recent Publications Resulting from This Research

- Neuromuscular Function: Comparison of Symptomatic and Asymptomatic Polio Subjects to Control Subjects. Agre JC, Rodriquez AA, Arch Phys Med Rehabil 71:545-551, 1990.
- Correlation of Motor Units with Strength and Spectral Characteristics in Polio Survivors and Controls. Rodriquez AA, Agre JC, Muscle Nerve 14:429-434, 1991.
- Motor Unit Firing Rates in Postpolio and Control Subjects During Submaximal Contraction. Rodriquez AA, Agre JC, Black PO, Am J Phys Med Rehabil 70:191-194, 1991.
- Neuromuscular Function in Polio Survivors at One-Year Follow-Up. Agre JC, Rodriquez AA, Arch Phys Med Rehabil 72:7-10, 1991.
- Physiologic Parameters and Perceived Exertion with Local Muscle Fatigue in Postpolio Subjects. Rodriquez AA, Agre JC, Arch Phys Med Rehabil 72:305-308, 1991.
- Electrophysiologic Study of the Quadriceps Muscles During Fatiguing Exercise and Recovery: A Comparison of Symptomatic Polios to Asymptomatic Polios and Controls. Rodriquez AA, Agre JC, Arch Phys Med Rehabil (in press).
- Intermittent Isometric Activity: Its Effect on Muscle Fatigue in Postpolio Subjects. Agre JC, Rodriquez AA, Arch Phys Med Rehabil (in press).
- Neuromuscular Function in Polio Survivors. An Invited Review Paper. Agre JC, Rodriquez AA, Orthopedics (in press).
- The Late Effects of Polio: Neuromuscular Function, a Critical Review of the Literature. An Invited Review Paper. Agre JC, Rodriquez AA, Tafel JA, Arch Phys Med Rehabil (in press).

[292] Aging with a Disability: The Late Effects of Polio

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Sponsor: National Institute on Aging, National Institutes of Health

Purpose—This research project sought to combine quantitative and qualitative methods in order to obtain an in-depth behavioral and sociocultural portrait of the compliance outcomes of 40 consecutive post-polio patients served at a rehabilitation hospital outpatient center.

Methodology—Forty subjects were selected from consecutive outpatients who participated in the National Rehabilitation Hospital's Post-Polio Program from July 1988 to June 1989. These 40 subjects were observed during their 2-day initial evaluation and at their 2-month follow-up evaluation at the National Rehabilitation Hospital. Thereafter, subjects were contacted by telephone and

given a structured interview once each year. In addition, 15 subjects for in-depth case studies, selected from interested volunteers from the consecutive outpatient sample, were given structured interviews at their homes and by telephone. Compliance outcomes were recorded and analyzed. Case study data were coded for content and themes.

Preliminary Results—Three behavioral categories of patients were identified. Some patients were motivated to make changes at the time of their clinical evaluation, and behavioral modification occurred within 6 months. Compliance-ready patients had clear agendas of the activities in their lives that were primary and other activities that fell into a less

significant category. Others were not ready to make these changes at the time of their clinical evaluation. By the end of the 3-year study, the compliance-delayed group had implemented at least two of the major interventions. Most of the compliance-resistant patients were overwhelmed by other life problems. In some cases, the polio-related disabilities played a significant role in producing the life problems, such as loss of job, troubled marriages, separation or divorce, additional difficulties or responsibilities with children or elderly parents, depression and other psychological disturbances. In other cases, ongoing psychological disturbances prevented compliance.

Two sociocultural subgroups of polio survivors were identified: 1) those for whom the late effects of polio are experienced as a "first disability"; and, 2) those for whom the late effects of polio represent a "second disability." The level of physical function

was not a predictor for membership in either subgroup. Shared polio traditions emerged during the epidemic years. Early polio traditions focused on the rehabilitation prescription to, "Put polio behind you;" "Push yourself physically until you reach your limits and then push some more;" and, "Use it or lose it." Late polio traditions, developing in response to the onset of secondary disabilities, involve a new pride in the American polio experience and function to validate the new rehabilitation prescription to, "Conserve it or lose it."

Future Plans—The project will be completed this year. Two articles will be submitted for publication.

Recent Publications Resulting from This Research

The Cultural Context of Polio Biographies. Scheer J, Luborsky ML, *Orthopedics* 14:1173-1181, 1991.

[293] Quantitative Assessment of Rehabilitation for Balance Impairment from Bilateral Vestibular Hypofunction

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Sponsor: *National Institute of Disability and Rehabilitation Research*

Purpose—The purposes of this investigation are to: 1) determine the efficacy of vestibular rehabilitation in patients with pure bilateral vestibular causes of balance impairment; 2) quantify and characterize the balance deficits of bilateral vestibular hypofunction (BVH) patients on standing posturography and activities of daily living (ADL) performance tests; and, 3) determine the relationship between standing and ADL stability characteristics in BVH patients. The major goals of this project are to determine specific, effective vestibular rehabilitation protocols for patients with vestibular-related balance dysfunction, as well as to determine the relationship of commonly-used balance tests to stability during meaningful activities of daily living.

Methodology—This is a randomized, prospective, measurement-blinded research design. Patient entry criteria include bilateral vestibulopathy evidenced by abnormal auditory canal caloric stimulation, sinusoidal vertical axis rotation, and dynamic

posturography (Equitest) test results. Each patient is tested at 0, 8, and 16 weeks after entry into the study. Half the patients receive vestibular rehabilitation between entry and the 8th week test, the other half between the 8th and 16th week test. Major outcome variables include full-body kinematic and kinetic (motion analysis laboratory) data during standing tests (feet apart, Romberg, and SemiTandem standing), and ADL tests (gait, stair ascent, and sit-to-stand). Equitest posturography data, Dizziness Handicap Inventory (a self-reporting symptom scale), and various clinical balance data ("get up and go," timed balance tests) are also analyzed.

Preliminary Results—We are currently beginning year 2 of this 3-year project. Patient self-reports reveal significant symptomatic improvement, especially during low-light locomotion (e.g., getting up at night) and during ADL in which the environment moves (e.g., riding a bus). The motion analysis lab

mediolateral and anteroposterior center of gravity data reveal improved whole-body control, forward velocity, double-support durations, and base-of-support widths following rehabilitation.

We are also examining trunk and head angular displacements and velocities, and center of gravity/center of pressure moment-arm to better characterize the locomotor stability deficits of these balance-impaired subjects. Results to date suggest this assessment model may be useful in testing other stability-deficient populations, and encouraging efforts are underway to apply the model to nonvestibulopathic patients.

Recent Publications Resulting from This Research

- Base of Support Characteristics During Gait. Lockert JD, Krebs DE, Riley PO, in Proceedings of the 7th Annual East Coast Clinical Gait Laboratory Conference, Richmond, VA, 1991.
- Biomechanical Analysis of Body Mass Transfer During Stair Ascent of Normal Subjects. Zachazewski JE et al., in Proceedings of the World Confederation of Physiotherapy, London, England, 1991.
- Dynamic Stability During Normal Gait. Krebs DE et al., in Proceedings of the 7th Annual East Coast Clinical Gait Laboratory Conference, Richmond, VA, 1991.
- Vestibular Dysfunction and Gait. Krebs DE, Lockert JD, in Mobility and Gait, B.S. Spivack (Ed.). New York: Marcel Dekker (in press).

[294] Pathophysiology of the Anemia of Chronic Renal Failure

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Sponsor: *National Institute of Diabetes and Digestive and Kidney Diseases, National Institutes of Health; University of Washington*

Purpose—This project is investigating why erythropoiesis remains suppressed in the majority of maintenance dialysis patients. Several hypotheses are under study, addressing the possibility that inhibitors remain in the patients' sera by not crossing the dialysis membrane, or that some aspect of treatment may independently lead to this problem.

Methodology—Studies will seek the presence of hypothesized inhibitors of erythropoiesis in uremic sera. Experiments will also seek to determine if repetitive red cell transfusions may cause the phenomenon, or if aluminum may have an inhibiting role in heme synthesis within the bone marrow. The applicability of using a dialyzer membrane of greater porosity will be studied, if the presence of inhibitors remaining in uremic sera is demonstrated.

Preliminary Results—It has been found that although a hypoproliferative anemia exists in all patients with chronic renal failure, some patients improve their anemia, though by an unknown means. In normal persons, it has been found that hypertransfusion and phlebotomy cause reciprocal changes in erythropoietin production and red blood cell production, though these effects may be absent or blunted during uremia.

Future Plans/Implications—If the basis for continued suppression of erythropoiesis during dialysis can be elucidated, it may point toward strategies to relieve this very serious consequence of kidney failure, or relieve what may be proven to be a serious side effect of treatment.

[295] Development of an Artificial Pancreas

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Sponsor: *National Institute of Diabetes and Digestive and Kidney Diseases, National Institutes of Health; University of Utah*

Purpose—This project concerns development of an artificial pancreas, with the ultimate purpose of

implanting it into diabetic patients whose own pancreatic functioning is severely reduced.

Methodology—A self-regulating insulin delivery system has been designed based on competitive binding between a glycosylated insulin derivative (SAPG-insulin) and glucose to a concanavalin A (ConA) polymeric gel substrate. The competitive binding of the two ligands for the substrates will regulate the glycosylated insulin release in relation to the outside glucose concentration, while the polymeric membranes, serving as a pouch system containing the insulin and gel, are used to regulate the permeability of glucose influx and insulin efflux.

Progress—The physicochemical properties of ConA gel have been determined. Mathematical models for the *in vitro* release of SAPG-insulin, based on its competitive binding against glucose, were developed and evaluated using experimental results. The performance of the polymeric pouch in the shape of a long hollow fiber was evaluated, and demonstrated improvement over previous arrangements. An evaluation of the equilibrium kinetics between the inside and outside of hollow fibers demonstrated that the

insulin release rate does respond to differing glucose concentrations outside the fiber, and differentiated the best insulin concentration to achieve this variable release.

Future Plans/Implications—Future work will be performed *in vivo*, which will also allow the assessment of biocompatibility of the materials. Efforts will be made to minimize the size of the fibers while maintaining sufficient SAPG-insulin release. It is hoped that these studies will contribute to the future development of a workable artificial pancreas, which can serve to rehabilitate diabetic patients whose pancreatic islet cell functioning has been severely reduced.

Recent Publications Resulting from This Research

A Self Regulating Insulin Delivery System Based on Competitive Binding of Glucose and Glycosylated Insulin. Seminoff LA, Kim SW, in *Modulated Controlled Release Systems*, J. Kost (Ed.). Boca Raton, FL: CRC Press, 1990.

[296] Analyzing Clinical Problems Involved in Organ Transplantation

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Sponsor: *National Institute of Diabetes and Digestive and Kidney Diseases, National Institutes of Health; University of Minnesota*

Purpose—This project involves a number of separate studies whose objectives are to analyze and isolate the clinical problems involved in organ transplantation, conduct clinical trials based on available data, and generate further experimental solutions to these problems. The organ transplant procedures encompassed in these studies are kidney and pancreatic islet cell transplants.

Methodology—The first aim is to prevent organ destruction by host. Toward this end, investigators are attacking problems of tissue typing, matching, and immunosuppression related to rejection, as well as problems of recurrent diseases, such as Epstein-Barr virus, that contribute to organ rejection. A

number of studies are comparing cyclosporine with other immunosuppressive therapies, including total lymphoid irradiation, for relative immunosuppressive success.

The second aim is to counteract infections, particularly those of cytomegalovirus, that occur as a result of the transplant operation or the handling of the donor organ. The third aim is to maximize rehabilitation of the recipient and donor patient after transplantation. The fourth aim is to maintain the patient and the organ in optimal condition prior to and during transplantation. Toward this end, investigators are attacking problems of hemodialysis, organ retrieval, and storage.

[297] Vestibular Stimulation and Cerebral Palsy

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Sponsor: Nemours Foundation

Purpose—The purpose of this work is to quantitatively analyze the effect of vertical accelerations on athetoid movement seen in cerebral palsy.

Progress—Using an arm tracking system, arm position data for eight cerebral palsied subjects (mean age=14.4 years) was collected at four intervals: before stimulation, immediately after stimulation, and at 15 and 30 minutes after stimulation. Stimulation consisted of 20 minutes of vertical reciprocal motion at an amplitude of 6 inches and an acceleration of 0.7g. Stimulation was performed with the subject seated in an upright posture.

Methodology—In order to accomplish our purpose, staff at the Alfred I. duPont Institute have constructed an electromechanical system that can apply a predetermined vertical acceleration to a child and his/her normal seating system. The researchers also have equipment which can accurately and precisely measure arm flexion and extension as the arm tracks a moving target. Using these two devices, a study

was conducted to evaluate voluntary movement of the forearm about the elbow joint in terms of its power spectral density. The study compared attributes of these densities before and after the subjects were stimulated in a controlled environment.

Results—Extensive statistical analysis of the data from seven tracking tasks using five measurement criteria has revealed that while there appear to be trends in the data toward more normalization of values after vestibular stimulation, no single task or measure has resulted in a statistically significant improvement.

The most interesting results have come from our examination of "holding still" tests. Six of our eight subjects showed a tendency toward a greater ability to remain in one position longer after vestibular stimulation than before. As in our other tests, the differences found in the data before and after stimulation were not statistically significant.

[298] PLEXUS: A Knowledge-Based System to Assist with the Diagnosis and Treatment Planning of Brachial Plexus Injuries

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Sponsor: None listed

Purpose—A knowledge-based system is being developed to assist neurologists and neurosurgeons with the diagnosis and treatment planning of patients with a brachial plexus injury (nerve injury in the neck). The reasons for developing this system are, among others, the very intricate anatomy of the brachial plexus and the relative unfamiliarity with the possibilities of modern neurosurgical techniques.

Progress—A knowledge-based system has been developed for diagnosis and treatment planning. This system uses production rules for a rough localization

of the injury and then uses a search algorithm to find the exact location of the injury. PLEXUS has a graphical user interface that allows easy data entry. In the previous year, work has focused on preparing for formal laboratory and field evaluations of the knowledge-based system.

Preliminary Results—The rule-based knowledge base has been tested clinically and has been shown to give correct advice for diagnosis and treatment plan in 80% of 15 cases. A double-blind test with the system has also been carried out. Although the

number of test cases is quite small, we may conclude that the knowledge-based system has a good performance. These results indicate the need to proceed with more formal evaluations of the system.

Future Plans/Implications—The knowledge-based system will be evaluated both in the laboratory and in the field. The laboratory test will involve an evaluation of the knowledge base with the cooperation of internationally renowned specialists in the field of brachial plexus injuries. For the field test, computers will be placed in five hospitals in the Netherlands for the period of 1 year. During this

year all patients with traumatic brachial plexus injuries who are seen by the physicians will be entered into the knowledge-based system. Performance, user friendliness, and acceptability of the system will be studied during this field test.

Recent Publications Resulting from This Research

Human-Computer Interaction with a Medical Knowledge-Based System. Van Daalen C, in Proceedings of the 1st European Conference on the Advancement of Rehabilitation Technology (ECART), Maastricht, The Netherlands, 1990.

Medical Decision Support: An Approach in the Domain of Brachial Plexus Injuries. Jaspers RBM, PhD diss., Delft University of Technology, 1990.

B. Arthritis

[299] Diagnosis of Cartilage Degeneration: Quantitative Surface Spectroscopy

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Sponsor: VA Rehabilitation Research and Development Service (Project #A656-RA)

Purpose—The long-term goal of this project is to develop a diagnostic device that can nondestructively quantify certain electromechanical and biochemical properties of articular cartilage that are related to structure and composition at the molecular level. These properties are significantly different in diseased cartilage (e.g., osteoarthritic) compared to normal tissue, even at the earliest stages of disease. These early, focal degenerative changes in cartilage cannot be detected by radiography or other methods of imaging. The device is intended as a spectroscopic sensor that can be used to detect focal cartilage degeneration at the time of arthroscopy or in open surgical procedures.

Preliminary Results—Preliminary studies have resulted in a prototype diagnostic device which can nondestructively detect molecular level changes that occur during cartilage degeneration. The prototype device consists of a "chip" that is placed on the surface of the cartilage. Injection of a very small electric current at the surface produces a mechanical

stress within the tissue that is detected by the probe; the magnitude and phase of the output stress is a precise reflection of tissue composition, integrity, and function. The objectives of follow-on research are to further extend and optimize the sensitivity of this device to have clinical value, and to test and evaluate the device in intact cadaver joints (animal and human) and in a canine model for cartilage degeneration.

Methodology—The specific tasks of the recently initiated project include: 1) validation of the measurement of the intrinsic tissue parameters (electrokinetic coupling coefficient, equilibrium modulus, and hydraulic permeability) using the surface spectrometer with standardized tissue specimens *in vitro*; 2) comparison of the current-generated mechanical stress measured in normal versus degenerated animal and human cartilage using the surface spectrometer with standardized specimens *in vitro*; 3) quantification of the ability of surface electromechanical spectroscopy to detect and locate focal,

model degenerative lesions created in cartilage specimens by selective enzymatic degradation of surface, deep, or full thickness regions. (These specimens will be tested with the surface spectrometer using short and long surface wavelengths and a wide enough range of frequencies to scan specific regions within the tissue); 4) fabrication of a surface spectrometer that can be used with intact joints via arthroscopic or open procedures—testing the surface spectrometer in cadaver joints (animal and human) in order to optimize sensor materials, electrode geometry, and other functions needed to achieve maximal sensitivity *in vivo*; and, 5) evaluation of the performance of the surface spectrometer in a canine model for cartilage degeneration (the anterior cruciate ligament transection, or ACLT model). *In vivo* sensor measurements will be made at graded

time intervals after ACLT, and the results will be correlated with histological, biochemical, electromechanical and biomechanical assessment of excised tissue specimens after sacrifice.

Implications—The significance of the research in progress is the potential for early detection and thereby early treatment of focal cartilage degeneration, prior to involvement of the entire joint. There is a compelling clinical need for such information on early degeneration: this information could facilitate conservative means for prolonging the time before which total joint replacement is required, such as appropriate physical exercise or surgical procedures involving abrasion arthroplasty, osteotomy, or the use of focal osteochondral allografts.

[300] Biochemical Analysis of Synovial Activation in Joint Dysfunction

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Sponsor: VA Rehabilitation Research and Development Service (Project #A052-6RA)

Purpose—This project has two aims. One is to examine pseudosynovia recovered from around aseptically loosened prostheses for the production of neutral metalloproteinases, prostaglandin E₂ (PGE₂), and interleukin-1 (IL-1). The other is to examine changes in protein kinase activity occurring during the early stages of synovial cell activation.

Methodology—To address the first aim, each pseudosynovial sample is divided in two. One half is into organ culture for 3 days, and the conditioned medium assayed for the mediators of interest. The other half is examined histologically following staining with hematoxylin and eosin.

Results—Of the pseudosynovia so far examined, several produce extremely high levels of the three mediators. However, they appear to be capable of independent regulation in that any one of them may

alone be present at a high concentration. Clinically, the highest amounts of IL-1 appear to be produced by areas of pseudosynovium adjacent to the most extensive loss of bone. PGE₂ and neutral metalloproteinases correlate less strongly with clinical evidence of osteolysis.

Histologically, the membranes contain a collagenous matrix within which are found fibroblastic cells, macrophages, lymphocytes, and sometimes giant cells. Particles of metal, bone cement, and polyethylene are present in many samples. The presence of polyethylene particles is associated with particularly high production of PGE₂, metalloproteinases, and IL-1.

Exposure of synovial fibroblasts to particles and IL-1 *in vitro* triggers extensive changes in the cellular phosphoprotein pattern, suggesting the activation of one or more kinases. Their identity is being actively investigated.

[301] Endurance Training with Management of Fatigue in Rheumatic Arthritis and Systemic Lupus Erythematosus

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Sponsor: National Institute on Disability and Rehabilitation Research

Purpose—The objectives of this study were to: 1) evaluate the long-term costs and effectiveness of aerobic training in improving fatigue, work capacity, and quality of life in rheumatoid arthritis (RA) and systemic lupus erythematosus (SLE); 2) define the physiologic and metabolic parameters of fatigue and their changes after conditioning; and, 3) define work ability and performance in patients with RA and SLE.

Fatigue is a common and disabling problem in RA and SLE. Previous trials in structured settings of aerobic training in these populations have suggested efficacy in improving endurance and reducing fatigue. We tested the effectiveness of an unsupervised home aerobic conditioning program for a relatively unselected, clinic-based population.

Methodology—Patients more than 18 and less than 50 years of age who satisfied the ARA Preliminary Criteria for RA or SLE, who reported fatigue, and who exercised fewer than three times per week were eligible for entry into the study. At entry, patients were evaluated for depression mood fatigue, helplessness, and demographics. Patients received a baseline electrocardiogram and complete blood and urine analyses, and performed a graded exercise tolerance test (ETT) using a bicycle ergometer.

Subjects were stratified by disease and randomized into exercise group or control group. Exercise group subjects received a bicycle ergometer for 12 weeks and were instructed to exercise three times a week for 30 minutes, maintaining a heart rate at 60% to 80% of their maximal rate. Compliance was monitored regularly by telephone; control subjects also received telephone calls. At the end of 12 weeks all subjects repeated all baseline tests.

Subjects were invited to participate in another 12-week unsupervised conditioning program which

included exercising three times a week for 30 minutes at a heart rate 60% to 80% of their ETT₂ heart rate. Bicycles were not provided. All participants in this second phase were contacted monthly to monitor compliance. Following this second 12-week period, subjects were given an endurance test and were asked to fill out all psychometric measures.

Results—Of the 75 subjects who entered the study, 71 completed baseline measures and were randomized (66 females, 5 males). Age ranged from 21 to 50 years old with a mean age of 37 years and a standard deviation of 8.0. Fifty-seven patients (29 RA, 28 SLE) completed the 12-week exercise program. Program effect was estimated with general linear models, controlling for selected baseline variables.

There were no significant differences between exercisers and controls on any of the variables at baseline. Average improvement in ETT was 5% in controls and 10% in exercisers, but the ETTs of the exercise and control groups at 12 weeks did not differ significantly after controlling for baseline fitness. Both exercise and control subjects showed less fatigue, depression, and perceived helplessness after 12 weeks. Although exercisers showed greater improvement in all three outcome variables, the differences between exercisers and nonexercisers were not significant when controlling for each variable at baseline. The RA exercisers consistently showed greater average improvement in all outcomes than other groups. Measures of disease activity were stable over the study.

In sum, under conditions representative of clinical practice (no on-site supervised training), prescribed exercise resulted in small, but insignificant, improvements in fitness, fatigue, and depres-

sion. This is in contrast to positive results of earlier studies in which on-site supervised exercise is the norm. The second 12-week exercise regime has not been evaluated at this time.

Recent Publications Resulting from This Research

Evaluation of a Controlled Trial of Home Aerobic Training in SLE and RA. Liang MH et al., presented at the Annual Meeting of the American College of Rheumatology in Seattle, WA, 1991.

C. Low Back Pain

[302] Identification of a Low Dimensional Representation of Lifting

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Sponsor: VA Rehabilitation Research and Development Center (Core Funds)

Purpose—Earlier research has noted that for many submaximal lifting tasks, the “human may be regarded as a ‘self-optimizing’ machine in which the biological system becomes coordinated to possibly accomplish a task with minimum energy expenditure, to maintain balance and to minimize pain.” Our goal is to identify kinematic or kinetic variables that might define such a relationship.

A clue to this relationship may lie in the fact that balance is required for proper lifting. When the body is balanced, there is a unique relationship between the center of gravity (COG), center of pressure (COP), and ground reaction force (GRF) vector. The relationship between these variables might be used to develop an invariant description of lifting dynamics since they also reflect the overall dynamic behavior of the biomechanical system. The purpose of our current study is to test this hypothesis.

Methodology—We use the WATSMART target point motion tracking system to record body segmental motion simultaneously with the GRF and the reaction forces acting through the handles of a loaded box. We also measure the locations of the posterior aspects of the calcaneus and distal ends of each subject's great toe to define his base of support.

The reaction force data are processed to obtain the trajectory of the body COG in the sagittal plane and the point of application of the ground reaction force (COP) in the horizontal plane. We use an inverse dynamic model to predict the reaction

torques at the hip, knee, and ankle joints using the three-dimensional target data and the reaction forces at either the free or fixed ends of the body (e.g., hands or feet). We also compute the axial compression force acting through lumbosacral disc.

Progress—We conducted a preliminary study to determine the feasibility of our hypothesis regarding an invariant relationship between the COG, COP, and GRF and the estimated joint torques at the lumbosacral junction and the lumbosacral disc compression force. In particular, we investigated a linear regression model for joint torques and disc compression force on the vertical components of the COG and GRF and the anterior/posterior trajectory of the COP. Accordingly, we conducted an experiment in which one subject lifted five different weights from the floor to knuckle height. He was allowed to choose the lifting style and repetition that he found most comfortable. He was instructed to place the weights back to their initial position at the end of each lift and return to an upright position to provide us with kinematic and dynamic data for unloaded cycles.

Preliminary Results—We found that there were linear combinations that accurately predicted the torque at the lumbosacral junction, the hip joint and, to a lesser extent, the knee joint. Likewise, there was a linear combination that accurately predicted the compression force acting through the lumbosacral disc (L5/S1). The first linear regression used the vertical displacement of the COG and the

vertical component of the GRF vector. The second linear regression added the anterior-posterior displacement of the COP as a third independent variable. There was excellent agreement between the predicted and actual joint torques and disc compression force. The shapes and magnitudes of the predicted torques calculated using either the fixed or free end models were in general agreement with values published in the literature. The results of the three-variable regression analysis showed that the greatest variance in the torque at the lumbosacral junction is due to the anterior-posterior component of the COP trajectory. The results of the two-variable regression analysis showed that the greatest variance in the torque at the lumbosacral junction is

due to the vertical displacement of the COG. The two-variable regression analysis accounted for 80 percent of the variance in the lumbosacral joint torque and disc compressive force. The curve fit was improved by adding the COP trajectory. In this case, 90 percent of the variance in lumbosacral joint torque and disc compressive force was explained by the three-variable regression model. The results of the other joints also followed this trend.

Recent Publications Resulting from This Research

Identification Of A Low Dimensional Invariant Function Of Lifting. Morris T, Trimble J, in Proceedings of the 14th Annual RESNA Conference, Kansas City, MO, 125-127, 1991.

[303] Quantification of Motion Characteristics in Low Back Disorders

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—The primary goal is to document 3-dimensional (3-D) trunk motion characteristics as a function of trunk asymmetry and create a database that describes the motion characteristics of the normal lumbar spine. The second goal is to quantify trunk motion characteristics for specific low back disorders. Results of the low back disorder patients are compared to normals and their progress during rehabilitation is monitored.

Progress—There are currently 220 subjects in the normal database. Subjects range in age from 20 to 65 years. We have recently been emphasizing our data collection in the older age categories (i.e., over 40). In the low back disorder group there are currently 90 patients, with 20 different diagnostic categories.

Methodology—The focus of this study is to quantify the changes in trunk motion characteristics as a function of asymmetry. An experiment was developed to investigate the manner in which 3-D trunk motion characteristics change as the trunk flexes and extends repeatedly in symmetric and asymmetric postures. The lumbar motion monitor developed at Ohio State University is used to measure 3-D trunk

motion characteristics. A display is shown to the subjects which indicates the amount of trunk twist (asymmetry) and a target twisting posture to maintain. Subjects are instructed to control their twisting, while flexing and extending as fast as they can.

Trunk asymmetry, the only independent variable in this study, has five levels: 1) zero (symmetric); 2) 15-degree twist to the right; 3) 15-degree twist to the left; 4) 30-degree twist to the right; and, 5) 30-degree twist to the left. The order of the left and right are counter-balanced.

There are nine trunk motion characteristics (dependent measures): 1) sagittal range of motion (difference between maximum position and minimum position); 2) frontal range of motion; 3) sagittal peak flexion velocity; 4) sagittal peak extension velocity; 5) sagittal peak flexion acceleration; 6) sagittal peak extension acceleration; 7) peak frontal flexion velocity; 8) peak frontal extension velocity; and, 9) peak frontal acceleration (both flexion and extension).

Results—Statistical results indicate that all sagittal plane motion characteristics decrease symmetrically (both left and right) as a function of increasing task asymmetry. Frontal plane motion characteristics

increase symmetrically as a function of increasing task asymmetry. Sagittal and frontal plane response patterns hold regardless of age.

The injured categories have different response patterns depending on type and severity of injury; for example, a right-sided herniated disc shows decreased trunk motion characteristics on the right side as compared to the normal database. In severely herniated disc cases (corrected by surgery), the amount of twisting is as small as 5 or 6 degrees prior to surgery. Spinal stenosis pre-surgery patients may show as little as 3 or 4 degrees of twisting. Most spondylolisthesis patients have the ability to twist to all five conditions; however, the sagittal plane motion characteristics have been less than that of a normal. Scoliosis patients show an increased response in frontal plane motion characteristics and a skewed sagittal plane pattern when compared to the normal group.

We have also tested cooperative injured patients

throughout their recovery process. The results of this portion of the study indicate that range of motion returns to normal first, followed by velocity and finally acceleration.

Future Plans/Implications—Our two main objectives are to monitor injured people throughout their rehabilitation process and enhance our number of older people in the database. One of our long-term goals is to quantify when someone is ready to return to work based on their performance in the series of five tasks and their job demands. In addition, we would like to use the lumbar motion monitor as a diagnostic tool for specific low back injury or back disorder groups.

Recent Publications Resulting from This Research

Three-Dimensional Dynamic Motor Performance of the Normal Trunk. Marras WS, Ferguson SA, Simon SR, *Industrial Ergonomics* 6:211-224, 1990.

[304] A Computer Program for the Analysis of Low Back Pain

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Sponsor: *None listed*

Purpose—A computer program is being developed to assist with the analysis of all the multifactorial aspects of low back pain, including not only the immediate presenting symptoms but also previous symptoms, family history, and social aspects such as occupation and lifestyle. The purpose of the work is to try and identify which factors are the most relevant, to eliminate any spurious information, and possibly also to detect trends in the epidemiology of low back pain.

Progress/Methodology—A suitable program has been written for logging the necessary data provided by each patient. Prior to this, information had been elicited from patients by a form of extended questionnaire, but no analysis of the data had been attempted. The initial program effectively transferred the questionnaire to a computer, with the expected advantage that logical inconsistencies could be avoided. For example, in the original questionnaire a patient could claim root pain at the start

among the general questions, yet deny it later in the same questionnaire when asked for details. This might be missed by the clinician, but a properly written computer program would not allow it. In fact, the detailed nature of the questionnaire permitted a number of such inconsistencies, and the major effort in the development of the initial program was their elimination. A first suite of analysis programs has now been developed to assess the data gathered, providing a frequency analysis of both individual characteristics and whole representing profiles. These can be carried out on a single patient to check on the changing symptoms with each visit, or may be used to correlate the pattern of presenting features for many patients. This analysis suite is currently undergoing assessment before further enhancements are attempted.

The program is currently written in BASIC for the BBC microcomputer, but an IBM version may be made available once the program suite is complete.

Preliminary Results—The program works well in the laboratory with imaginary patients, but this is only in the hands of the author. The program suite has

therefore now been passed to the clinical environment for independent use.

D. Swallowing Disorders

[305] Assessment of the Swallow Reflex in Patients with Dysphagia

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Sponsor: VA Rehabilitation Research and Development Service (Project #C443-RA)

Purpose—The purpose of this project has been to develop a nonradiographic method by which investigators can study certain aspects of swallowing. Of particular interest was application of the electroglottograph (EGG) to evaluation of certain temporal aspects of the pharyngeal stage of swallowing. The EGG was originally developed as a noninvasive, electrical method of measuring vocal fold contact during phonation; application of the EGG to swallowing was previously unexplored. Ultimately, the results of the investigation will provide information to assist in determining appropriate rehabilitation techniques and in evaluating progress for patients with oropharyngeal dysphagia.

Results—Frequency responses of two EGGs were studied. The output from the Fourcin EGG was found to be amplitude-modulated and frequency-dependent. At low frequencies associated with swallowing, the Fourcin output was the derivative of the change in neck impedance. Simultaneous measures of EGG, oropharyngeal pressure and video-fluoroscopy were used to validate the Fourcin EGG.

The output from the EGG manufactured by Glottal Enterprises was found to be neither amplitude-modulated nor frequency-dependent. This electroglottograph has four electrodes which make it easier for the examiner to find correct placement and track laryngeal movement.

Simultaneous measures have been made with the EGG. Simultaneous ultrasound and EGG revealed that when the echogenicity from the hyoid reached maximum displacement, the EGG signal represented maximum conductance. Simultaneous

EGG and videoendoscopy showed that laryngeal elevation, represented by the EGG signal, preceded vocal fold approximation.

The relationship between vallecular residue and oral stage dysphagia, and reduced hyoid elevation and movement of the epiglottis, was studied in 330 patients. Patients with vallecular residue were more likely to have oral involvement or deviant epiglottic function, characterized by an absence of epiglottic inversion or incomplete inversion, than patients without vallecular residue. Patients with deviant epiglottic function were more likely to have oral involvement, reduced hyoid elevation, or vallecular residue than patients without deviant epiglottic function; patients with reduced hyoid elevation were more likely to have oral involvement than those with normal hyoid elevation. Multivariate analysis revealed that the relationship between oral involvement and deviant epiglottic function, present in the bivariate analysis, was not significant when controlling for other relationships in the model. The relationship between primary medical diagnostic category and the presence/absence of vallecular residue as well as the other dichotomous variables varied between and within diagnostic categories.

Additionally, we have studied the relationships between aspiration and the four variables listed above, along with delayed initiation of the swallow reflex, pyriform sinus stasis, hypopharyngeal stasis, incomplete vocal fold closure, and reduced laryngeal elevation. In the 330 patients we studied, each independent variable was strongly associated with the presence of aspiration. A linear trend was exhibited among the ordinal variables; the more

severe the variable, the more severe the aspiration. Of those patients with epiglottic dysfunction, the patients who exhibited base of tongue approximation to the epiglottis, or who exhibited no epiglottic movement, were most likely to aspirate.

Recent Publications Resulting from This Research

Comprehensive Clinical Examination of Oropharyngeal Swallowing Function. Perlman AL et al., in *Seminars in Speech and Language*, 12, B. Sonies (Ed.). New York: Thieme Medical Publishers, Inc., 1991.

Frequency Response of the Fourcin Electroglottograph and Measurement of Temporal Aspects of Laryngeal Movement During Swallowing. Perlman AL, Liang X, *J Speech Hear Res* 34(4):791-795, 1991.

Neurology of Swallowing. Perlman AL, in *Seminars in Speech and Language*, 12, B. Sonies (Ed.). New York: Thieme Medical Publishers, Inc., 1991.

Use of the Electroglottograph for Measurement of Temporal Aspects of the Swallow: Preliminary Observations. Perlman AL, Grayhack JP, *Dysphagia* 6(2):88-93, 1991.

The Relationship of Vallecular Residue to Oral Involvement, Reduced Hyoid Elevation and Epiglottic Function. Perlman AL, Grayhack JP, Booth BM, *J Speech Hear Disord* (in press).

[306] Effects of Thermal Stimulation on Dysphagia After Stroke

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Sponsor: VA Rehabilitation Research and Development Service (Project #C485-RA)

Purpose—The objective of this research is to determine the influence of thermal stimulation on dysphagia resulting from stroke.

Progress/Methodology—Patients with medical evidence of multiple cardiovascular accidents (CVA) and videofluoroscopic evidence of a delay in the pharyngeal response were invited into the treatment study. The treatment involved intensive thermal stimulation. The study design was one of withdrawal with each patient serving as his own control.

All appropriate patients were hospitalized for one month and began with baseline and diagnostic neurologic and swallowing testing. Each subject was randomly assigned to either an ABAB or BABA sequence (A=no thermal stimulation, B=thermal stimulation). Each stage lasted for one week. Progress testing occurred on the last day of each A and B period. All subjects received an exit videofluoroscopic examination and follow-up testing at one month.

All patients who agreed to participate in the study received a baseline videofluoroscopic swallowing examination, using six 3-cc liquid boluses. Each patient also underwent four progress videofluoroscopic examinations and one 30-day follow-up videofluoroscopic examination using three 3-cc liquid boluses to complete the data collection phases of the study. Visual perceptual and computer-based visual image processing analysis of these swallows

were completed as methods to establish treatment efficacy.

Preliminary Results—Twenty-two subjects completed the protocol. Results for the first seven have been published. Results for these seven patients failed to provide strong evidence for the efficacy of thermal stimulation in patients who are dysphagic from multiple CVAs. Data from the final 15 patients have been analyzed and are being prepared for publication. These data also failed to provide strong evidence for the efficacy of thermal stimulation. However, enough small changes in swallowing function were reported to warrant further research. One such follow-up study began in October 1991. In addition, the software which was written to allow the computer-based visual image processing of swallowing images has been described twice in the literature. A beta site for this software has been established at the National Institutes of Health. Several other centers, including several in the VA system, are soliciting this software.

Recent Publications Resulting from This Research

Image Processing in Swallowing and Speech Research. Dengel G, Robbins J, Rosenbek JC, *Dysphagia* 6:30-39, 1991.

Effects of Thermal Application on Dysphagia After Stroke. Rosenbek JC, Robbins J, Fishback B, Levine R, *J Speech Hear Disord* (in press).

Interactive Image Processing in Swallowing Research. Dengel G, Robbins J, Rosenbek JC, *Comput Uses Speech Hear* (in press).

E. Vascular Disorders

[307] Reducing the Error in Estimated VO_2max During Treadmill Testing with Handrail Support

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Sponsor: *Comprehensive Rehabilitation Center, Rehabilitation Medicine Service and Cardiology Service, VA Medical Center, Northport, NY; Department of Community and Preventive Medicine, State University of New York, Health Science Center, Stony Brook, NY*

Purpose—Errors in estimated VO_2max during submaximal and maximal exercise have been identified elsewhere when handrail support was permitted. In the literature search conducted, no studies published on this topic attempted to control the amount of handrail support during a maximal symptom limited treadmill stress test. The purpose of this study is to reduce, if not eliminate, the difference between measured and estimated VO_2max by *limiting*, but not eliminating handrail support.

Progress/Methodology—Data is presented on 47 subjects in 94 tests. Generally healthy males (Group I), and females (Group II), and patients with (Group III), and without (Group IV) myocardial infarction who possess coronary artery disease, completed two symptom limited treadmill tests using the modified Bruce protocol. Volunteers were randomly assigned to take one of two treadmill tests, TDM HS—treadmill test with handrail support limited to the tips of two fingers of one hand and TDM NH—treadmill test without handrail support. Twelve lead ECG, heart rate (HR), blood pressure (BP), oxygen

consumption (VO_2), Rating of Perceived Exertion (RPE), and symptoms were monitored and recorded throughout both tests.

Preliminary Results—Within each group between TDM HS and TDM NH, there was no significant difference in percent of predicted (220 minus age) HR, $\text{HR} \times \text{systolic BP}$, measured maximal VO_2 or respiratory exchange ratio. Estimated VO_2max was calculated from exercise duration using previously published equations. Although exercise time was greater in Groups II, III, and IV, measured VO_2max did *not* significantly differ in Groups I, II, and IV from the estimated VO_2max when handrail support was limited to the tips of two fingers of one hand.

Future Plans—Testing will continue until an adequate sample size has been obtained for each group. Prediction of VO_2 at submaximal as well as maximal exercise will be compared against measured values. Regression equations generated from these groups will be tested against previously published equations.

X. Oncology

[308] Test for Chemotherapeutic Sensitivity of Cerebral Gliomas: Use of the Colorimetric MTT Assay

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Sponsor: Surdna Foundation; W.W. Smith Foundation

Purpose—This study was undertaken to evaluate the colorimetric MTT (3-(4,5-dimethyl-2-thiazolyl)-2,5-diphenyl-2H tetrazolium bromide) assay as a means of testing the sensitivity of gliomas to chemotherapeutic agents *in vitro*.

Methodology—Eight human glioma cell lines were plated in 96-well tissue culture plates and incubated for 4 days with 10 different anticancer agents; 5 different concentrations of each drug were tested. The MTT dye was then added to the wells, and the resulting formazan precipitate was solubilized with dimethylsulfoxide (DMSO). The spectrophotometric absorbance (measured at 570 nm) of control and experimental wells was used to calculate the cytotoxicity index (CI). Values with a CI greater than 50% growth inhibition indicated cytotoxic efficacy (sensitivity to the chemotherapeutic drug).

Preliminary Results/Implications—The MTT assay failed to reveal drug sensitivity in one-eighth of the tumors tested. Six of the other seven (85.7%) glioma cell lines were highly sensitive at varying concentrations to doxorubicin, mitomycin C, and cisplatin. Four of the seven (57.1%) cell lines demonstrated intermediate sensitivity to vinblastine and mitoxantrone. Five of the seven (71.4%) cell lines exhibited resistance to BCNU, bleomycin, Cosmegen, and etoposide.

The MTT assay provides a rapid and relatively simple method of *in vitro* screening of established glioma cell lines for cytotoxicity against a broad spectrum of chemotherapeutic agents. Further assessment will be needed in the future to determine if cell cultures produced from fresh tumor biopsies of individual patients can be readily produced for testing with the MTT assay.

[309] Antitumor Effect of Externally Applied Low-Level Direct Current on Fibrosarcoma Tumor Model

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Sponsor: Ministry of Science and Technology, Slovenia

Purpose—Our purpose was to optimize the antitumor effect of externally applied low-level direct current (DC) on fibrosarcoma Sa-1 murine tumor model, confirmation of the antitumor activity on additional melanoma B-16 murine tumor model, and testing DC for cytotoxicity on an *in vitro* model.

Progress—Different current levels and current polarities were employed in a single-shot treatment of murine tumors delivered through single and multiple Pt-Ir needle electrodes in order to optimize the electrical parameters of tumor treatment. The research was expanded and enriched with experimental work on the *in vitro* model.

Methodology—A single-shot treatment of 30, 60, and 90 minutes' duration with cathode(s) inserted directly into the tumor site, anode(s) subcutaneously in the tumor vicinity (cathodic electrotherapy), and vice versa (anodic electrotherapy), was performed on two different murine tumor models (fibrosarcoma Sa-1 and malignant melanoma B-16) grown subcutaneously at the back of the mouse. *In vitro* cells were suspended in 30 ml culture medium and were subjected to low-level DC delivered via the Pt-Ir alloy electrodes immersed into the suspension for one hour; after this treatment, cells were transferred to Petri dishes. The immediate cytotoxic effect of the DC was evaluated by cell counting three and 48 hours after treatment, and compared to control (percent of control), and the surviving fraction was determined by a colony-forming ability test.

Results—Better response of tumors to cathodic electrotherapy was recognized through the observation of tumor growth, as well as through the histological examination of tumor sections. In cathodic electrotherapy, sharp delineation between centrally located (around the electrode insertion site) necrosis and distal vital parts was noted. Different susceptibility of tumors tested to electrotherapy was found. In melanoma B-16 at 1.8 mA of one-hour duration single-shot electrotherapy with three cathodes inserted into the tumor site and two anodes

subcutaneously in its vicinity resulted in 40% cure rate, whereas in fibrosarcoma Sa-1 no cures were achieved at the same regime. DC employed under *in vitro* circumstances proved to have moderate immediate cytotoxic effect (percent of control) with negative correlation to DC level. The surviving fraction expressed the same dependence to DC level and was 1.0 at DC < 0.2mA, 0.6 at 0.6mA and 0.4 at 1.0mA when the cells were cultured in the same medium in which they were treated, whereas when new culture medium was added to the cells after treatment, the surviving fraction was somewhat higher, especially at DC from 0.6mA to 1.0mA.

Future Plans—Different electrode material will be used in the future, and more emphasis will be given to the *in vitro* experiments. *In vivo* treatment combined with interleukin IL-2 will also be carried out.

Recent Publications Resulting from This Research

- Tumor Bioelectric Potential and Its Possible Exploitation for Tumor Growth Retardation. Miklavcic D, et al., J Bioelectr 9:133-149, 1990.
- The Effect of Low Level Direct Current on V-79 Cell Line In Vitro. Batista U, et al., Period Biol 93:225-226, 1991.
- Prospectives of Cancer Treatment by Direct Current. Miklavcic D, et al., Med Biol Eng Comput 29 (Supp. Part 1):89, 1991.
- Non-Thermal Antitumor Effect of Electrical Direct Current on Murine Fibrosarcoma Sa-1 Tumor Model. Miklavcic D, et al. In: Electromagnetics in Medicine and Biology. C.T. Brighton, S.R. Pollack (Eds.), San Francisco: San Francisco Press (in press).

[310] Living with Homecare: Cancer Patients and Their Caregivers

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Sponsor: National Cancer Institute, National Institutes of Health

Purpose—Recent efforts at cost containment have contributed to a shift from hospitalizing cancer patients who are receiving radiation therapy to offering these services on an outpatient basis. With the shift to homecare comes a number of problems. Little documentation exists on the health care service utilization patterns of cancer patients living at home, the extent to which existing services and insurance coverage meet their needs, their levels of satisfaction with services, their health care expenses, and the impact of outpatient care on patients and their families.

Methodology—Adult cancer patients who were undergoing radiation therapy were recruited into the study. Criteria for entry included: age 30 years or older, high likelihood of ongoing care needs related to cancer and cancer treatment, life expectancy of at least 1 year, and noninstitutional residence. Patients (and their primary caregivers) are interviewed three times at 4-month intervals. Major variables include demographic data, physical health and functional status, psychosocial variables (such as measures of depression, stress, optimism, and social support), the need for homecare and other services, and the

costs of medical care incurred by the patients and caregivers. Caregivers are asked about the amounts of stress and burden they experience, as well as for medical and homecare services for the patient. Medical records are examined to collect information on diagnosis, type and site of cancer, prior therapy

and outcomes, medications prescribed, and changes in health care status.

Progress—The study is currently in its final stages of data collection, and preliminary analyses of the data are in progress.

[311] Cricopharyngeal Myotomy Study

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Sponsor: *National Cancer Institute, National Institutes of Health*

Purpose—This study will attempt to answer on a prospective basis whether performance of a cricopharyngeal myotomy improves swallowing. This surgical procedure has been purported to improve dysphagia from a variety of illness.

Progress/Methodology—This multi-institutional and multi-year trial continues to accrue patients. To date, approximately 70 patients have been entered.

The subjects for this trial are patients with squamous cell carcinoma following the supraglottic larynx and the base of the tongue. This population is anticipated to suffer with dysphagia following standard treatment. The randomization of the study is between performance of a cricopharyngeal myotomy versus no myotomy. The primary methodologic tool is videofluoroscopy.

XI. Orthopedic Implants

A. General

[312] Bone Ingrowth and Remodeling with Porous Coated Implants

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Sponsor: VA Rehabilitation Research and Development Service (Project #A501-RA)

Purpose—The purpose of this work is to formulate a comprehensive theory consistent with many features of skeletal growth and development, maintenance, regeneration, and degeneration. The results of our previous investigations indicate that tissue stress histories play a major role in regulating the biology of skeletal tissues and that these influences are stronger and appear earlier in skeletal development than has been previously thought. The equations used to predict cartilage, bone, and mesenchymal tissue biology are similar to those that account for mechanical energy dissipation or the accumulation of fatigue damage in all materials. Our results may thus reflect fundamental characteristics of the transduction of mechanical energy to chemical energy in living organisms. The context in which this work is being conducted is porous coated/bony ingrowth prosthetic replacement of the proximal femur and tibia. The end product of this research will be a consistent framework of computer analyses which can be applied to predict the biological events associated with initial ingrowth and subsequent bone remodeling. We anticipate that it will be possible to apply these approaches to the design and evaluation of any implant in the body.

Methodology—In the course of our investigations, we will generate three-dimensional finite element models of the variety of human bones and joints. The loading history over some period (e.g., an "average" day) will be specified by a series of discrete load cases applied for a specific number of load cycles. The entire bone will initially be represented by a solid, homogeneous structure with a

constant bone density. Using a time-incremental bone remodeling technique, we will remodel the computer models to create an internal distribution of bone density and morphology which conforms to our bone remodeling theory. The resulting prediction of bone density distributions will be compared with those measured from cadaveric specimens. Our theory and computer approaches may then be modified so that our predictions correlate better with normal bone anatomy.

The bone and joint models will then be altered to represent the initial implantation of various uncemented porous coated components. In some models, a thin layer of pluripotential tissue will be represented at the bone/prosthesis interface. The multiple loading, stress history approach will then be applied and the differentiation of the interface tissue will be predicted. Using different stress history criteria, we will thus predict the extent and locations of bone ingrowth along the interfaces. Our criteria will be adjusted and varied parametrically to represent the types of results which have been observed by others in experimental animal studies and clinical retrievals. Subsequent bone remodeling around the prostheses will be calculated using the same algorithms which had been previously verified for the normal tibia and femur.

Future Plans—Two additions to our remodeling algorithms are being developed. The first is the incorporation of anisotropy and the second is the development of an inverse remodeling algorithm that will allow us to predict the makeup of the

loading histories which lead to realistic bone morphologies.

Recent Publications Resulting from This Research

An Approach for Time-Dependent Bone Modeling and Remodeling—Application: A Preliminary Remodeling Simulation. Beaupre GS, Orr TE, Carter DR, *J Orthop Res* 8:662-670, 1990.

An Approach for Time-Dependent Bone Modeling and Remodeling—Theoretical Development. Beaupre GS, Orr TE, Carter DR, *J Orthop Res* 8:651-661, 1990.

Computer-Aided Implant Design Using Bone Remodeling Algo-

rithms (Abstract). Orr TE, Beaupre GS, Carter DR, First World Congress of Biomechanics II:192, 1990.

Computer Predictions of Bone Remodeling Around Porous-Coated Implants. Orr TE, et al., *J Arthroplasty* 5(3), 1990.

Femoral Bone Architecture Computed from 3-D Models Relating Bone Remodeling to Stress Histories (Abstract). Orr TE, Beaupre GS, Carter DR, *Orthop Res Soc* 15:77, 1990.

Mechanical Stress Histories and Connective Tissue Differentiation (Abstract). Carter DR, et al., First World Congress of Biomechanics II:80, 1990.

Numerical Methods for Emulating Stress-Induced Remodeling in the Femur (Abstract). Beaupre GS, Orr TE, Carter DR, First World Congress of Biomechanics II:200, 1990.

[313] Fracture Healing and Bone Remodeling in Plated Long-Bones

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Sponsor: VA Rehabilitation Research and Development Service (Project #A294-2RA)

Purpose—The objectives of this study are to develop models of the fracture-healing process for both conservatively treated and internally plated long-bone fractures.

Methodology—Both mathematical and experimental models of fracture healing are used to study the fracture-healing process. The mathematical models utilize the finite element technique. Models of conservatively treated long-bone fractures and plated long-bone fractures have been developed. An osteogenic index is used to predict the regions of a fracture callus that will ossify first.

Laboratory models will be used to assess the efficacy of using shortened screws at the outer screw locations compared with using full-length screws for plated fractures. A strain gage based torque-measuring screw driver has been designed to monitor the insertion and removal torque of the screws which attach the fixation plate to the bone.

Results—Finite element models of plated long-bones show that slippage between the plate and the bone influences to a great extent the amount of stress shielding. Plate slippage is a direct function of screw tightness. A time-dependent, incremental remodeling program has been developed to predict the changes in density distribution caused by the implantation of

orthopaedic implants. Preliminary models of nonplated long-bones subjected to bending, axial, and torsional loads have been analyzed.

In the experimental phase of the study, plates have been applied to phenolic tubes modeling the human radius. The use of bicortical end screws results in a plated bone construct that is stronger in the bending-closed loading mode, stronger in the torsional loading mode, and weaker in the bending-open loading mode.

Future Plans—The use of the bone remodeling algorithm of Carter and colleagues will allow the prediction of changes in the density distribution caused by plate fixation.

Recent Publications Resulting from This Research

An Approach for Time-Dependent Bone Modeling and Remodeling—Application: A Preliminary Remodeling Simulation. Beaupre GS, Orr TE, Carter DR, *J Orthop Res* 8:662-670, 1990.

An Approach for Time-Dependent Bone Modeling and Remodeling—Theoretical Development. Beaupre GS, Orr TE, Carter DR, *J Orthop Res* 8:651-661, 1990.

Mechanical Stress Histories and Connective Tissue Differentiation (Abstract). Carter DR, et al., First World Congress of Biomechanics II:80, 1990.

Numerical Methods for Emulating Stress-Induced Remodeling in the Femur (Abstract). Beaupre GS, Orr TE, Carter DR, First World Congress of Biomechanics II:200, 1990.

[314] Effect of Surgical Fit on the Biological and Mechanical Response to Porous-Surfaced Implants

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Sponsor: VA Rehabilitation Research and Development Service (Project #A136-3RA)

Purpose—The purpose of this study was to investigate the effects of a uniform gap space between a porous implant and surrounding bone upon the resulting bone growth into the porous surface, and upon attachment strength. Implants with and without a plasma-sprayed hydroxylapatite (HA) coating were evaluated in regions of cancellous and cortical bone.

Methodology—Femoral intramedullary implants were constructed by threading Ti-6Al-4V alloy porous coated discs of 6.0, 8.0, 9.0 and 10.0mm diameters onto a central 2mm threaded rod. Each implant consisted of four 4.0mm thick discs of each diameter, separated by solid acrylic spacers 10.0mm in diameter and 2.0mm thick. The assembled implants were approximately 100.0mm in length. Three different disc arrangements were used at each time period, allowing two discs of each diameter to reside in cancellous (metaphyseal) region and cortical (diaphyseal) regions of the femur.

The animal model used was the skeletally mature mongrel canine ranging in weight from approximately 18 to 22kg, and radiographically screened for proper femoral size. Implants of identical configurations were inserted bilaterally into the femoral intramedullary canal using standard aseptic techniques. The femoral canal was carefully prepared by sequential hand reaming to a diameter of 10 mm. Combined with the implant diameters, this resulted in uniform gaps of 0, 0.5, 1, and 2 mm. Implantation periods of 4, 8, 12, 24, and 52 weeks were used, with five animals per time period; at each time period two animals received uncoated implants bilaterally, and three animals received one HA-coated and one uncoated implant for paired comparisons.

The harvested femora were sectioned transverse to the long axis through the acrylic spacers to produce individual test specimens. Using a specially designed fixture that supported the surrounding bone to within 150 μ m of the interface, the

specimens were pushed-out at a displacement rate of 1.27 mm/min to determine interface attachment strength. All specimens were processed using standard undecalcified histologic and microradiographic techniques. The histologic sections were analyzed using a computerized video analysis system. The amount of maturing new bone in apposition to and within the porous implant surface was quantified, as well as the amount of the original gap filled by new bone.

Results—Attachment strengths were observed to increase with increasing implant diameter (decreasing gap size) for both uncoated and HA-coated implant types. Uncoated samples of each diameter showed increasing attachment strength from 4 to 52 weeks; HA-coated samples of each diameter showed similar increases in strength from 8 to 52 weeks.

Analysis of variance (ANOVA) demonstrated that interface shear strength was significantly affected by time of implantation, implant diameter, and the presence of the HA coating (all $p < 0.005$). There was no significant effect upon attachment strength due to placement in cancellous versus cortical bone ($p = 0.45$).

In comparing paired uncoated and HA-coated samples, at each time period for all implant diameters, mean interface strengths for the HA-coated samples were greater than for the uncoated samples. Significant differences were observed at 8 weeks for the 9 mm diameter implants (mean difference = 1.102 MPa, $n = 8$, $p < 0.025$), and 10 mm diameter implants (mean difference = 3.125 MPa, $n = 8$, $p < 0.02$). Significant differences were also observed at 12 weeks for the 9 mm diameter implants (mean difference = 1.072 MPa, $n = 6$, $p < 0.05$). The HA coating is therefore effective in significantly enhancing attachment strength in the presence of initial gaps 1 mm or smaller.

At 8 and 12 weeks, HA-coated implant strengths were higher than the next largest uncoated implant diameter (e.g., 6 mm with HA versus 8 mm

uncoated), in all cases except for 9 mm with HA versus 10 mm uncoated. At 24 and 52 weeks increasing implant diameter (decreasing gap size) increased attachment strength regardless of the presence of the HA coating. None of these changes, however, were statistically significant.

Histologic analysis indicated increased gap filling and bone ingrowth for HA-coated samples compared with uncoated samples at all time periods. These increases were greatest during early time periods and for implants with a 1 mm or less gap. At later time periods, the increased bone ingrowth was maintained.

Implications—Ideally, a porous-surfaced implant relying on bone ingrowth fixation should make initial apposition with the surrounding bone. This is not always achieved surgically at all locations, and spaces between the implant and bone result. These may be due to deficiencies in implant design, instrumentation design, or surgical technique. The use of an HA coating onto the porous coating was shown to have a significantly positive effect on attachment strength and bone ingrowth.

[315] Effects of Treatment for Heterotopic Bone Formation on Biological Fixation

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Purpose—The purpose of this study is to investigate the effects of several combinations of short-term and chronic postoperative indomethacin therapies upon the amount of bone growth into a porous surface and the bone-porous implant attachment characteristics.

Heterotopic ossification following total hip replacement is a frequently reported complication. Treatments include radiation and indomethacin therapy. Clinically, indomethacin has been shown to be effective in reducing ectopic bone formation, and to be effective in preventing heterotopic bone formation induced by demineralized bone matrix. Recent studies have indicated chronic indomethacin preoperatively may significantly reduce the amount of bone growth into a porous surface and reduce bone-porous implant attachment strength. Since indomethacin is used as an anti-inflammatory drug, the question arises as to which postoperative therapies might prohibit effective bone-porous implant attachment.

Methodology—The femoral transcortical implant model was used in skeletally mature mongrel dogs. Cylindrical Ti-6Al-4V implants (5.1mm in diameter by either 18mm or 20mm length) coated with a two-layer spherical bead Ti-Al-4V porous coating

were placed in the femora through both cortices; each animal received five or six implants bilaterally. After the appropriate time the implants were harvested and subjected to mechanical push-out testing to determine interface attachment strength. Intact and tested samples were evaluated using standard undecalcified and microradiographic histologic techniques. Implantation periods included 3, 6, 12, 18, and 24 weeks. The experimental design resulted in 26 treatments (combinations of drug/implantation time) to be evaluated. All animals (except controls) received 1.0 mg/kg/day of indomethacin given orally in two divided doses. Blood was drawn at regular intervals during therapy to confirm blood indomethacin levels. Animals were randomly assigned to the following drug groups: controls—no drugs; chronic—indomethacin begun 2 weeks preoperative and each day until sacrifice; heterotopic—indomethacin immediately postoperative and each day for 6 weeks; 3-week delay—indomethacin each day beginning 3 weeks postoperative until sacrifice; 6-week delay—indomethacin each day beginning 6 weeks postoperative until sacrifice; 9-week delay—indomethacin each day beginning 9 weeks postoperative until sacrifice; 18-week delay—indomethacin each day beginning 18 weeks postoperative until sacrifice.

Results—For each of the seven drug treatments there was a significant effect of time of implantation upon shear strength (all $p < 0.0025$), with strength values strictly increasing over time. Only at the 3-week time period was there a significant decrease in strength due to the indomethacin. At the 12-week time period there were no significant differences in strengths among the drug groups. At the 24-week time period the chronic group strengths were significantly greater than all other groups. Quantitative histologic analysis demonstrated no significant differences in percent bone ingrowth among the groups at the 3- and 6-week time periods. Percent bone ingrowth measurements exhibited no clear trends at 12, 18, and 24 weeks. For the therapies evaluated,

indomethacin given strictly postoperatively had equivocal effects upon interface attachment strength. No consistent detrimental effect upon fixation strength was observed. It was unexpected that animals receiving chronic indomethacin would exhibit greater strength values. Longer periods of preoperative indomethacin therapy or higher postoperative dosages appear required to consistently reduce attachment strengths. It is also possible that the detrimental effect of indomethacin given in the immediate postoperative period is a short-term phenomenon. While the effects of indomethacin given strictly postoperatively remain unclear, strengths appear to be unaffected by a delay of 6 weeks or longer.

[316] Coatings/Surface Treatments for Prosthesis-Bone Bonding

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Sponsor: VA Rehabilitation Research and Development Service (Project #A654-RA)

Purpose—The goal of this research is the development of prosthetic coatings/surface treatments for fixation to the musculoskeletal system through bone-bonding. Calcium-containing coatings produced by two methods and a surface treatment produced by a third method will be evaluated with respect to the bond strength between the coating/surface treatment and the metallic substrate, and the time course and strength of bone-bonding. The hypothesis is that ion beam sputtering and ion-implantation methods produce bone-bonding coatings and surface treatments with significantly higher bond strengths to titanium alloy than achieved with plasma-spraying.

A major problem associated with the use of internal skeletal prostheses is the fixation of the device to bone. Deficiencies in current methods of fixation limit the function and longevity of total joint replacement prostheses, and also limit the possibilities for attachment of external prosthetic devices through percutaneous fittings affixed to bone. Recent studies have indicated that bone will bond (chemically) to a variety of calcium-containing substances. Currently, orthopedic and dental interests are focused on the implementation of calcium phosphate (so-called hydroxyapatite) coatings that

have been plasma-sprayed onto titanium alloy prostheses. However, investigations indicate that the strength of attachment of the plasma-sprayed coating to the metallic substrate degrades with time, and thereby can lead to detachment of the coating. Detachment of the plasma-sprayed coating can lead to loosening of the prosthesis and the abrasion of the fragments of the coating against the titanium alloy device. There is a need for coatings or surface treatments that allow for bone-bonding, but that have a higher strength and longer lasting bond to the metallic substrate than the current plasma-sprayed coating.

Methodology—The experimentation is to include:

- Production of 1) an hydroxyapatite coating using an ion beam sputtering (S) method and 2) a calcium-containing surface treatment by ion-implantation (I). Titanium alloy will be the metallic substrate. Analysis of the elemental composition of the coating/surface treatment will be performed by electron spectroscopy for chemical analysis (ESCA, also referred to as x-ray photoelectron spectroscopy, XPS). The crystalline structure will be determined by x-ray diffraction.

- Determination of the bond strength of the coatings to the titanium alloy substrate using torsion and push-out tests before and after immersion in phosphate-buffered saline. A commercially available plasma-sprayed (P) hydroxyapatite coating will serve as the control.
- Determine the time course of bone-bonding to cylindrical specimens with the experimental (S and I) and control (P) coatings in a canine model. Bone-bonding will be quantified biomechanically and histologically.

Progress—Titanium alloy specimens coated with a commercially available plasma-sprayed hydroxy-

apatite coating have undergone x-ray diffraction analysis. The results demonstrate that there is noncrystalline calcium phosphate present as well as a small percentage of non-apatitic crystalline material (probably tricalcium phosphate) in the coating. The constituents will affect the solubility of the coating. Studies are in progress to utilize a "scratch" test to determine the strength of attachment of the coating to the underlying metallic substrate. Hydroxyapatite coatings are being applied to titanium alloy specimens using sputtering procedures.

[317] Bone Substitute Material

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Purpose—The goal of this research is the development of a bone substitute material. Bone grafts are often required during reconstructive orthopedic, maxillofacial, craniofacial, oral, and plastic surgery procedures. Often more bone graft is required than can be obtained from the patient (autogenous bone). Problems with allograft bone (from other individuals) include: 1) transmission of disease; 2) difficulty of procurement and processing; 3) uncertain immune response; and, 4) premature resorption. Recent studies have focused on the production of synthetic calcium phosphate ceramic materials as bone substitutes. However, these substances do not undergo physiological resorption and remodeling, and because of their high stiffness can lead to undesirable changes in surrounding bone. There is need for a bone substitute material that behaves more like natural bone.

The central hypothesis is that natural bone mineral particles (e.g., 1-2 mm in diameter) prepared by deorganifying bovine bone (anorganic bone) can serve as an effective off-the-shelf bone substitute material by virtue of their osteoclast-mediated resorption and replacement by host bone, and their stiffness, which more closely resembles natural bone than synthetic calcium phosphate ceramics. A second hypothesis is that the compres-

sive strength of anorganic bone particles in osseous defects increases rapidly within 6 weeks as new bone incorporates the particles. A third hypothesis is that as anorganic bone is heat-treated to increase the strength of the substance, the material becomes nonresorbable as a result of the increasing crystallinity, behaving more like synthetic hydroxyapatite ceramic.

Methodology—The following tasks are being undertaken:

- Natural bone mineral particles, 1-2 mm in diameter, are being prepared by deorganifying bovine bone. Two heat treatments of 600° C and 1,200° C are being employed to produce higher strength material with a more crystalline hydroxyapatite structure. These three specimens and commercially available synthetic hydroxyapatite ceramic will undergo elemental analysis using electron spectroscopy for chemical analysis (ESCA) and x-ray diffraction study to determine crystalline structure. Mechanical testing of the particulate specimens will be performed using a confined compression test.
- The animal model—a cylindrical hole drilled in the medial aspect of the condyle of the rabbit knee—will be employed to compare histologically

the amount of bone formation on the surface of the anorganic bone and synthetic particles (approximately 1 mm in diameter) after 2, 6, and 52 weeks. The percentage of the surface of the particles undergoing osteoclast-mediated resorption will also be determined.

- The compressive strength of defects filled with particles of the experimental and control materials will be determined.

Progress—In order to determine the effect of age on the bone regeneration within defects in our animal model, the amount of new bone formed within

defects of young (6-month) and old (2-year) rabbits is being determined. Holes, 3.5 mm in diameter and 8 mm deep, were drilled in the medial aspect of the condyles of both knees of 11 young and 10 old animals. Five animals in each group were sacrificed after 3 and 10 days; the one remaining animal in the young group was killed after 1 day. The left knees were embedded in polymethylmethacrylate for ground section histology and the right knees decalcified and embedded in glycol methacrylate for microtomy. Histology specimens are undergoing evaluation.

[318] Enhancement of Bone Ingrowth into Porous Implants by Hydroxyapatite Coatings

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Sponsor: VA Rehabilitation Research and Development Service (Project #A356-2RA)

Purpose—The effects of hydroxyapatite coatings on porous implant fixation appear to be affected by factors such as solubility of the coating, crystallinity, and surface porosity. This study compares the bone response to three coatings of varying solubility and density.

Methodology—Calcium phosphate (CaP) coated porous implants were inserted into the supracondylar region of the distal canine femur (Beagle) and subjected to pull-out testing at periods of 2, 4, and 6 weeks after implantation. Histologic analysis of bone ingrowth was determined by quantitative histomorphometry of back-scattered electron microscopy of randomly selected implants from each group.

Results—No implants became infected. The solubility of the CaP coatings as measured by dissolution in EDTA was $\text{CaP3} > \text{CaP5} > \text{CaP4}$. Crystallinity of the coatings, determined by x-ray diffraction and infrared spectroscopy demonstrated CaP3 to be more than 90 percent hydroxyapatite structure, CaP4 to be amorphous tri- and tetracalcium phosphates, and CaP5 to be amorphous alpha tri- and tetracalcium phosphate compounds.

No difference in quantity of bone ingrowth was detected on histomorphometric analysis. CaP5 specimens examined by back-scattered electron microscopy consistently demonstrated debonding of the ceramic coating from the porous substrate. CaP3 and CaP4 coatings produced statistically significant enhancement of fixation relative to the CaP5 coating.

[319] Evaluation and Examination of Retrieved Porous-Coated Orthopaedic Prostheses

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Sponsor: VA Rehabilitation Research and Development Service (Project #A473-DA)

Purpose—The overall objective of this study is to assess the long-term feasibility of porous coating as

a mechanism for fixing orthopaedic prostheses to bone.

Methodology—Retrieved prostheses are fixed in formalin for 48 hours, examined macroscopically for both soft and hard tissue apposition to the prosthesis, and mapped for the location of this tissue. The prosthesis is coarsely sectioned and the large sections are dried in a series of alcohol and acetone solutions. Fully-dried prosthetic components are embedded in ethyl-methacrylate and cut into sections approximately 1 mm thick. These sections are handground to between 20 and 40 μ m in thickness and hand polished. Specimens are stained with either hematoxylin and eosin (H and E) or acid phosphatase, cover-glassed, and photographed on a Zeiss photomicroscope III. The interface is mapped and evaluated for bone and fibrous tissue ingrowth, osteoblastic and bone resorptive activity, and the presence of polyethylene or metal wear debris.

Preliminary Results—In the past 12 months, we examined 604 retrieved prostheses of which 318 were porous coated. One hundred and eighty-two porous-coated hip prostheses were received from 124 surgeons. One hundred and thirty-six porous-coated knee prostheses were received from 87 surgeons. Eleven of the 318 porous-coated prostheses were retrieved post-mortem from cadaver specimens. In the first 3 years of this project, we examined more than one thousand joint replacement components made available to us from a surgeon base of more than 400 participants.

Bone ingrowth of large and small pore sizes of both titanium and cobalt alloy was demonstrated. The amount and extent of bone ingrowth was found to be a function of implantation duration, implant design, and fixation mechanisms.

Of those device types evaluated, bone ingrowth of femoral hip prostheses, femoral knee prostheses, and patellar prostheses was frequently seen; bone ingrowth of acetabular prostheses less frequently seen; and bone ingrowth of tibial prostheses least frequently seen. Tibial prostheses with porous-coated central pegs demonstrated bone ingrowth of the central peg more frequently than ingrowth of the porous-coated plateau. The most frequent bone ingrowth of the underside of the tibial plateau was seen with prostheses fixed with four metal screws. However, there was generally evidence of metal fretting between the screws and the screw holes and

polyethylene debris generated by contact between the screws and the underside of the bearing surface.

Fatigue failure of polyethylene articular surfaces and the development of significant amounts of polyethylene wear debris was seen in a high percentage of knee prostheses. Mechanisms of failure of patellar and tibial components included: separation of polyethylene from the metal backing, wear-through of the polyethylene, cracking, pitting, and delamination of the articulating surface as well as deformation of the polymer due to creep. Examination of the ingrowth surfaces of tibial and patellar prostheses which had been retrieved for reasons of polyethylene failure often demonstrated polyethylene wear debris at the margins of the porous coating which appears to be associated with localized osteoclastic activity and bone resorption.

Based on our discovery of corrosion at that interface in a series of mixed-metal components last year, we have expanded our examination of the morse taper junctions found between the head and neck of modular hip prostheses. To date, we have examined 139 modular hip prostheses of which 11 were comprised of titanium alloy heads on titanium alloy stems, 88 were comprised entirely of cobalt alloy, and 48 had cobalt alloy heads on titanium alloy stems. Corrosion of the taper was seen only in the mixed-metal systems. Twenty-five of the 48 mixed-metal systems presented corrosion with the extent of surface involved statistically correlated with the duration *in vivo*. All of the mixed-metal modular hip systems *in vivo* for greater than 40 months presented corrosion.

We believe that the corrosion is of the crevice-type which is galvanically induced by the potential developed between the cobalt and titanium alloys whose passive films have been broken. This study is ongoing with the goal of determining the ramifications of these initial findings.

Recent Publications Resulting from This Research

- Biomechanical Problems of Polyethylene as a Bearing Surface. Collier JP, et al., Clin Orthop 261:107-112, 1990.
- Early Failure of Polyethylene Components in Uncemented Total Knees. Surprenant VA, et al., Poster presentation at the 57th Annual Meeting of the American Academy of Orthopaedic Surgeons, New Orleans, LA, 1990.
- Osseointegration of Titanium Implants in Total Hip Arthroplasty. McCutchen JW, Collier JP, Mayor MB, Clin Orthop 261:114-125, 1990.

The Success of Pegs, Stems and Screws as Adjuvant Means of Fixation of Tibial Prostheses as Measured by Radiographic and Histological Examination. Collier JP, et al., presented at the 57th Annual Meeting of the American Academy of Orthopaedic Surgeons, New Orleans, LA, 1990.

Examination of Porous-Coated Patellar Components and Anal-

ysis of the Reasons for Their Retrieval. Collier JP, et al., J Appl Biomat 2:95-99, 1991.

Results of Implant Retrieval from Postmortem Specimens in Patients with Well-Functioning, Long-Term Total Hip Replacement. Collier JP, et al., Clin Orthop 274:97-112, 1992.

[320] Development of a Strain Gauge Bonding Process Using a Hydroxyapatite Coating

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Sponsor: National Science Foundation

Purpose—Long-term *in vivo* bone strain measurements would be useful in remodeling studies as well as clinically for characterization of bone deformation at bone-implant interfaces and as a feedback system for muscle stimulators for paraplegics. Preliminary work using hydroxyapatite (HA) coated gauges placed on the lateral aspect of a greyhound femur showed good bonding after 4 months. The current study was designed to further develop this technique and determine the bonding rate.

Methodology—The sensing surface of uniaxial strain gauges were coated with a 15 wt% polysulfone solution applied using an aerosol propellant. The coated side of the gauges were placed onto HA powder. Orthomatrix (OM) HA, which was more amorphous and less spherical and CeraMed (CM) HA, which was more crystalline and highly spherical, were used. Because of packing efficiency differences, the polysulfone layer was allowed to set for 1 versus 5 minutes for the OM HA and CM HA, respectively, to obtain a coating thickness between 40 and 50 μ m. Gauge coating interfaces were tested in tension and shear.

Three groups of 3 male greyhounds aged 24-28 months, weighing 28-38 kgs were selected. During sterile surgery several gauges were placed on the lateral aspect of their femora. In each case, uncoated gauges were placed using the standard glue technique and coated gauges were placed with circumferential sutures.

Following explantation, new glue-down gauges were attached to the left femora as controls. Left and right femora were cantilever-loaded at 1.2 kg/s to 10 kg. The measurements obtained from the

gauges were plotted as a percentage of the control at 3, 6, and 12 weeks.

The femora were embedded using a procedure previously reported. Cross-sections were taken perpendicular to the long femoral axis for BSE and light microscopy. The rate of bone growth was estimated using tetracycline labeling.

Results—The interfacial strength between gauge and coating was 4.39 ± 1.37 MPa for the CM HA and 12.21 ± 2.00 MPa for the OM HA in tension and 4.55 ± 0.69 MPa and 5.98 ± 1.49 MPa, respectively, in shear.

No gross changes were apparent on explanted femora. The ability of the glued-down gauge to take accurate measurements was reduced between 0 and 3 weeks dropping to approximately 20% capacity and between 6 and 12 weeks where the gauges became completely detached. An increase in bonding for both HAs occurred during this time period; however, the less crystalline, more amorphous OM HA bonded to the bone at a faster rate, reaching nearly 93% of measurement capacity at 12 weeks. The increased rate of bonding for the OM HA may be attributed to the difference in the materials properties of the HA powders, including crystallinity differences or particle shape and size distribution.

Preliminary histological results at 4 months indicate that there are several areas of HA in contact with the bone, and areas without contact show signs of new bone formation. Less bonding was noted at the shorter time periods. Fibrous tissue was noted between gauge and bone adjacent to all glue-attached gauges.

B. Hip

[321] High Viscosity Cooler Acrylic Bone Cement

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Sponsor: VA Rehabilitation Research and Development Service (Project #A143-3RA)

Purpose—Absolute long-lasting rigid fixation of total joint prostheses is essential for clinical success. The conventional (original) use of polymethyl methacrylate (PMMA) was, for the most part, successful in the short term and in the elderly. Conversely, failure rates due to aseptic loosening when original cementing techniques were utilized were unacceptable in the long term, the young, and in the revision setting. Efforts to attack this problem have occurred on two fronts: cementless fixation and modifications of cement technique. In our lab, we have concentrated on modifying cement technique.

Progress/Methodology—Over the past year, we have completed a project evaluating the regional distribution of bone-cement interface shear strength and a project evaluating the effect of varying cement viscosity and injection pressure on bone-cement interface shear strength. We currently are initiating an *in vivo* study on the effect of injection pressure on shear strength of the bone-cement interface, bone ingrowth, and bone necrosis using a goat model.

In the first project mentioned above, 12 fresh adult human proximal femora underwent neck osteotomy, canal reaming, plugging, high-pressure saline lavage, and retrograde injection of bone cement (Howmedica Simplex P). The cement was then pressurized to 20-50 psi. After curing of the cement, the femora were sectioned into eight horizontal slices of 10 mm thickness beginning at the superior aspect of the lesser trochanter. These slices were then further sectioned into 5 × 10 mm blocks at the anterior, posterior, medial, and lateral aspects of the slice. The bone-cement interface in each of these sections was then tested to failure in shear using a servohydraulic testing device. The results of this study showed that there were both longitudinal and circumferential variations in bone-cement interface

strength, with the strongest interfaces being proximal-medial and the weakest being distal-lateral. We feel that the combination of high cement strains and weak bone-cement interfaces suggests that the distal aspect of a femoral prosthesis is most vulnerable to cement loosening. This can be correlated with clinically observed modes of prosthetic failure.

In the second project completed over the past year, 45 proximal femora were prepared as described above, except that 4 different cementing techniques were used. These included two different pressures (mean of 8 psi vs. mean of 27 psi) and two different viscosities (standard cement and cement mixed with 25% less liquid monomer). Specimens were prepared as described above, and the medial and lateral aspects of the first two slices were tested for bone-cement interface shear strength. The results of this study revealed that cement pressure is a relatively more important variable in controlling shear strength than cement viscosity. We also showed that the bone-cement interface strength was strongly dependent on cancellous bone shear strength. The relationship of interface shear strength with cement penetration into cancellous bone was complex, i.e., incremental increases in cement penetration do not necessarily lead to incremental increases in interface shear strength. We feel that techniques incorporating pressurization of higher viscosity cement in the femoral canal may optimize bone-cement interlock while minimizing adverse effects of excessive cement penetration.

Our current project is an *in vivo* study evaluating the effect of varying the cement injection pressure in cemented femoral components in total hip arthroplasty. We are using a goat model and evaluating the new bone growth, bone necrosis, and bone-cement interface shear strength after arthroplasty utilizing high- and low-pressure cementing techniques.

[322] Quantitative Analysis of Total Hip Arthroplasty on Stress and Strain

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Purpose—The need to evaluate total hip arthroplasty design continues. Assessment of new design features requires quantitative comparative data to understand the effects of both design and materials selection on host-implant interaction following implantation. With the dependence on biological ingrowth and long-stem stability becoming a major concern as implants survive longer, this project originally focused on the use of various strain gauge evaluation methods to assess the change in bone strength following implantation of prostheses of various designs. Automated strain gauge evaluation of acetabular component performance has been completed. More recently, the study of the proximal femur and its reaction to femoral component implantation is being carried out.

Progress/Methodology—The thrust of the current research investigation is to develop a non-contact, full-field optical method of strain analysis of the proximal femur. Toward this end, initial holographic interferometric evaluations have been carried out to provide a qualitative assessment of the strain following press-fit femoral component implantation. These early results detail discontinuities at the distal tip of the prosthesis and support clinical observations. Over the last year, we have spent considerable effort developing a quantitative evaluation method. Speckled shearing interferometry (SSI) has been used to meet this goal. SSI has a simple

optical setup, relaxed vibration isolation requirements, and more controllable ranges of sensitivity. In addition, it allows optical differentiation of displacement data to obtain strain information.

The major drawback for this system is the need for double-exposure photographic methods of data analysis. Despite this drawback, accuracies of ± 4 percent were found on a prototype system. The nonplanar aspects of bone, however, led to significant defocusing errors. Successful control of these systemic errors using smaller lens opening and exposure times has negated some of these early problems, and further computerized analysis is being performed to increase efficiencies.

To further automate the system, an automatic video-based data acquisition protocol is being developed. This method eliminates the need for photographic plates and their processing and allows for electronic filtering of the frequency modulated speckle patterns, thus improving the ability to assess location of fringes and subsequent strain measurement. This new method also allows for evaluation/quantification of the strain changes resulting from press-fit, porous-coated devices with various geometric configurations, including off-the-shelf designs and custom prostheses. These results will help the original goal of providing quantitative information on the effect of these new implants and their design features on femoral bone strain immediately following implantation.

[323] Patient Management and Rehabilitation Protocols Following Major Hip Surgery Based on Quantitative In Vivo Data

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Sponsor: VA Rehabilitation Research and Development Service (Project #A352-2RA); National Institute on Disability and Rehabilitation Research

Purpose—Surgical reconstruction or replacement of the human hip joint following trauma or arthritis is a very common occurrence, involving (in the United States alone) over 400,000 people each year. The surgical procedures include total replacement of both femoral and acetabular components of the natural joint with artificial prostheses, replacement of only the femoral component (usually following femoral neck fracture), and osteotomies where the natural components of the joint are retained but realigned. Whatever the intervention, the patients must be managed during an immediate postsurgical period of immobility, then progress through a transitional process of rehabilitation that takes them, in stages, through more demanding movement patterns until they regain full gait capability and can perform other activities of daily living. The patient management and physical therapy protocols applied throughout this process are essentially similar, whatever the particular hip surgery. Subjective generalizations derived from past experience with similar patients determine the optimum ordering, best postoperative time for initiation, appropriate duration, and content of each protocol of these management and rehabilitation practices. Thus, protocols which are vital to the rapid, safe, and full recovery of the patient rest solely on qualitative observations and *ex post facto* outcomes. *De novo* quantitative objective data are now available to evaluate these traditional processes and to consider alternatives.

Progress—Novel data from a pressure-instrumented femoral head replacement procedure has now provided objective, quantitative information on the mechanical environment of the human hip joint during surgery, postoperative management, throughout the process of rehabilitation, and in the activities of daily living. These data are challenging contemporary patterns of patient care, therapy, and rehabilitation, and provide objective data on which to

classify the strenuous character of many normal and common movement patterns.

Methodology—A pressure-instrumented prosthesis with 14 small sensors integral with the spherical, metal, pseudo-femoral head measures the focal pressure experienced by acetabular cartilage as it articulates against the femoral component. The first unit was implanted in June 1984. Data were acquired during surgery, postoperative recovery, immobilization, mobilization while in bed, early muscle exercise, all stages of ambulation (i.e., parallel bars, walker, crutches and cane), and then during normal gait and other movement patterns such as rising from a chair, stair-climbing, jumping, and jogging, for a total period of over 5 years. During movement protocols, the pressure data are complemented with 6-degree-of-freedom kinematic data from the body segments of the lower extremity and the pelvis, and the foot-floor forces measured on dual forceplates. Very high local pressures measured during certain movements indicate significant muscle co-contraction, which has been confirmed from concurrent electromyographic data from the major muscle groups crossing the hip joint.

The pressures measured during the various stages of recovery and rehabilitation are of direct relevance to the evaluation of traditional rehabilitation procedures. Much of the data demonstrate inconsistencies with what has been presumed to be meritorious and commonly accepted rehabilitation practice, both in ordering and timing. To cite several examples, most present immobilization practices produce higher maximum pressures than peddling a stationary bicycle, a common early mobilization procedure. Muscle contraction exercises performed in bed, well before attempts at ambulation, produce pressures of the same magnitude as those during the stance phase of level walking measured a year postoperative. Little correlation exists between the

recorded maximum pressures and the current sequence in ambulation therapy (i.e., first parallel bars, then walkers, then crutches, then canes). The measured hip pressure is little affected by the force applied to the partial-load-bearing cane. The maximum pressures measured during walking indicate no further rise after 6 months, which correlated with the clinical observation of achieving normal gait. The highest pressure measured was 18 MPa when rising from a normal (45 cm) chair. Astoundingly, this pressure is higher than that produced when a hydraulic jack lifts a car.

Implications—These new quantitative pressure data can provide the basis for a more rational definition of appropriate protocols applied during recovery and rehabilitation following major hip surgery. The longitudinal data may explain why acetabular protrusion sometimes occurs following femoral head replacement. We believe the congruence of the metal ball to the natural acetabular cavity—both diameter and geometry—is critical, as demonstrated in our *in vitro* studies. The new data also are influencing surgical practice by indicating the directions of maximum pressure; accordingly, surgeons are using bone grafts to strengthen challenged regions of the pelvis.

Future Plans—A second pressure-instrumented prosthesis that incorporates a number of design improvements is ready for implantation. A future, more extensive series of implants have been proposed that would augment the pressure data with direct measurement of the force vector across, and the moments about, the hip joint.

Recent Publications Resulting from This Research

- An Instrumented Prosthesis for Measuring Pressure on Acetabular Cartilage In Vivo. Mann RW, Burgess RG, in Proceedings of the Workshop on Implantable Telemetry in Orthopaedics, Berlin, 65-74, 1990.
- Comparison of Paced and Unpaced Constrained Chair Rise Maneuvers. Riley PO, et al., in Proceedings of the IEEE Engineering in Medicine and Biology Society Conference, Philadelphia, PA, 2146-2147, 1990.
- Influence of Age on Dynamics of Rising from a Chair. Schenkman ML, et al., in Proceedings of the East and West Coast Gait Laboratories Conference, San Diego, CA, 1990.
- In Vivo Pressures on Acetabular Cartilage Following Endoprosthesis Surgery, During Recovery and Rehabilitation, and in the Activities of Daily Living. Mann RW, Hodge WA, in Proceedings of the Workshop on Implantable Telemetry in Orthopaedics, Berlin, 181-204, 1990.
- Modelling the Biomechanics of Posture and Balance. Riley PO, Hodge WA, Mann RW, J Biomech 23:503-506, 1990.
- Whole-Body Movements During Rising to Standing From Sitting. Schenkman M, et al., Phys Ther 70(10):638-651, 1990.
- Exercise and Gait Effects on In Vivo Hip Contact Pressures. Krebs DE, et al., Phys Ther 71(4):301-309, 1991.
- Biomechanics of a Constrained Chair Rise. Riley PO, et al., J Biomech (in press).

[324] Rehabilitation Implications of In Vivo Hip Pressure Measurements

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Sponsor: VA Rehabilitation Research and Development Service (Project #A352-2RA)

Purpose—How cartilage distributes the time- and position-varying load across a synovial joint is of interest clinically as it relates to the longevity of endoprosthesis implantation following femoral head or neck trauma or necrosis. Migration of the implant through the acetabular cartilage is common; a 50% incidence of protrusion 4 years postoperatively has been reported. Pathologically, cartilage pressure distribution is central to the possible role of mechanical factors in the etiology of osteoarthritis, acting either directly (e.g., collagen fiber rupture), or through mechanical/biological coupling (e.g., the

influence of the mechanical micro-environment on chondrocyte metabolism and expression). Scientifically, pressure distribution information is a crucial element in the basic understanding of how the mechanical and biological characteristics of cartilage, bone, and synovial fluid synergize locally and globally to achieve high load capacity, low-friction, long-wearing skeletal bearings.

Prior to our research, only sparse *in vitro* data from rather gross experiments were available on the magnitude and distribution of contact stress in synovial joints. In general, these studies described

the natural global joint as distributing the load vector into a more-or-less uniform or axis-symmetrical distribution, with maximum pressures not much higher than that calculated by dividing estimates of the load magnitude by estimates of the area of interarticular cartilage contact. This "average" pressure is about 2 to 3 megapascals (MPa).

Cartilage *per se* is a relatively soft, poroelastic matrix which is saturated with fluid. When small plugs of cartilage are loaded so as to permit fluid drainage, the intrinsic or network modulus is measured at less than 1 MPa. Mathematical models of simplified joints studying fluid circulation have in fact postulated free-draining or porous sliders, influenced apparently by the plug experiments.

Methodology—After considering different approaches to experimentally quantify local pressures and their distribution in the human hip joint, we chose to integrate multiple pressure transducers into the load-bearing surface of a pseudo-femoral head, in part because hemiarthroplasty is a common surgical response to femoral head or neck damage. Thus *in vivo* instrumented endoprosthesis data are relevant to a significant patient population and the surgeons who service them. These data are also pertinent to scientific understanding of normal and pathological synovial joint tribology and the etiology of osteoarthritis.

Results—The first prosthesis was implanted in 1984, and produced extensive data for over 5 years (see project "Patient Management and Rehabilitation Protocols Following Major Hip Surgery Based on Quantitative In Vivo Data").

A second prosthesis has been complete for some time and is sterilized awaiting the identification of a suitable patient. Significant design improvements have been incorporated based on experience with the first implant. The distribution of the 14 pressure transducers has been changed to include those locations on the femoral head which consistently reported data of interest as the subject performed a wide range of movements and loading patterns. The mounting of the single-silicon-crystal cantilever beams, the flexion of which measures cartilage pressure, was changed. The first design called for epoxy cementing, which exhibited cold flow and

calibration deterioration on several of the transducers after several years. An all-mechanical clamping technique which eliminates this problem was devised and extensively tested. This new arrangement also facilitates the precalibration adjustment of the beams relative to the pressure diaphragms and the interconnecting push-pins.

Separate *in vitro* studies of temperature rise by "walking" human cadaver hip joints in the Hip Simulator had indicated significant temperature rise. Subsequent biochemical studies on chondrocyte response to these temperature rises caused the expression of "heat-shock" proteins. The Berlin group has recently reported similar temperature rise *in vivo* from their force-instrumented total hip replacement prosthesis. To better monitor temperature on and in the endoprosthesis, a dummy pressure transducer diaphragm was added and instrumented with a thermister. This detector will also be used in a feedback control system to reduce the power inductively transmitted from the external coil to the antenna on the stem of the prosthesis.

The electronic package which converts the pressures, expressed as the strain-gauge signals, from the individual flexing beams to a pulse-amplitude-modulated signal for frequency modulation telemetry outside the human body, was extensively redesigned. Restudy resulted in part from changes and improvements in electronic components since the original unit was designed (large-scale integrated circuit "chips") and in part to increase the number of channels from 16 to 32 to accommodate the temperature measurements, the power feedback control, and the future force vector and moment measurement.

Future Plans—A third prosthesis is underway. The major mechanical components are complete and fabrication will commence subsequent to implantation and completion of the early experiments with the second unit. During surgery, postsurgical management, and early rehabilitation, much data are acquired, which requires the participation of all staff, with other tasks and assignments postponed.

Implications—Data from the second and the third prostheses will inform the consistency of data across subjects under similar experimental conditions.

Recent Publications Resulting from This Research

An Instrumented Prosthesis for Measuring Pressure on Acetabular Cartilage In Vivo. Mann RW, Burgess RG, in

Proceedings of the Workshop on Implantable Telemetry in Orthopaedics, Berlin, 65-75, 1990.

[325] Optimized Surface Bonding and Stiffness of Femoral Endoprostheses

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Purpose—The objective of this investigation is to determine the optimal surface characteristics and material properties for a femoral endoprosthesis to avoid loosening. The specific short-term objectives are to investigate the following design parameters using finite element modeling techniques: 1) surface distribution of bone-prosthesis bonding for porous or ceramic-coated stems; 2) elastic modulus of the prosthesis; 3) stem design, including the shape and the presence of a collar for calcar contact; and, 4) the role of Coulomb friction at the bone-prosthesis interface.

Progress—A three-dimensional (3-D) finite element model of an intact femur was developed which was then modified to include a conventional straight-stem femoral component with a collar for calcar contact. A third 3-D model was developed by replacing the straight-stem component with a contemporary canal-filling femoral stem. The applied loads represented three phases of gait, stair ascent, and various isometric exercises. Constraint equations were defined at the bone-implant interface to simulate bone ingrowth at porous-coated surfaces or bone bonding at hydroxyapatite-coated surfaces. Nonlinear gap elements were used to simulate frictionless contact where the stem was not coated. A mathematical scheme for optimization of the distribution of bone-implant bonding was developed and successfully applied to the 3-D model of the canal-filling titanium prosthesis. Additional analyses employing cobalt-chromium and carbon composite implants are in progress.

To investigate the role of friction at the bone-implant interface, a 2-D model of the same

canal-filling prosthesis and femur was developed. To establish solution procedures, an axisymmetric stem in diaphyseal bone was analyzed using axisymmetric models and plane stress models with side-plate elements. These models included nonlinear contact surfaces; unlike the gap elements used in the 3-D models, these contact surfaces are capable of large displacements and include Coulomb friction. A novel solution technique employing constraint equations along with side-plate elements was developed to best account for the 3-D structural behavior using a 2-D model.

Methodology—Computer-based 2-D and 3-D structural models are employed using the finite element method. Iterative solution procedures for optimizing the distribution of bonding between the bone and the implant have been developed. The 3-D models include nonlinear gap elements to represent frictionless contact at the stem surface. More general nonlinear contact surface algorithms, which include Coulomb friction and large relative displacements, are also employed in the 2-D models.

Results—A technique based on mathematical optimization was developed and applied to a canal-filling titanium femoral component of total hip arthroplasty. Two constraint equations were defined using interface shear strengths from published push-out tests of porous-coated implants and using estimated values of micromotion from clinical follow-up studies of uncemented femoral stems. The objective function to be minimized employed a linear combination of the peak shear stress and peak shear relative motion at the bone-implant interface

and the peak difference in bone effective stress relative to the corresponding effective stress predicted for the intact femur. Application of these criteria to the femoral component indicated that extension of the bonded surface of the prosthesis to the endosteal surface of the proximal cortical diaphysis greatly enhanced the overall stability.

Further extension of the bonding reduced the interface micromotion, but increased the interface shear stresses such that the corresponding constraint was exceeded. Various small refinements of the bonded surface distribution did not result in further reduction of the objective function beyond the value obtained with a uniform distribution over the proximal surface. The optimal solution appeared to have a bonded area in the range of 60 to 75% of the total stem surface area.

Future Plans—Our current objective is to apply the same optimization methods to the canal-filling prosthesis with the properties of cobalt-chromium and of a carbon fiber-reinforced polymer substituted for those of titanium to test the hypothesis that the

optimal distribution of bone bonding is a function of the stiffness of the prosthesis. The optimization method will also be applied to our 3-D model of the conventional straight-stem femoral component. The studies of the relationships between Coulomb friction and subsidence and micromotion, employing the 2-D finite element models, will also be completed.

Recent Publications Resulting from This Research

Parametric Analysis of the Interface Mechanics and Material Properties of a Straight-Stem Femoral Component for Total Hip Arthroplasty. Cheal EJ, et al., First World Congress of Biomechanics, 11:229, 1990.

The Effects of Porous Coating Distribution on the Femoral Component of a Total Hip Replacement. Wang CW, Cheal EJ, Spector M, Transactions of the Orthopaedic Research Society, 16:268, 1991.

Role of Loads and Material Properties on the Mechanics of the Proximal Femur After Total Hip Arthroplasty. Cheal EJ, Spector M, Hayes WC, Transactions of the Orthopaedic Research Society, 16:512, 1991.

Role of Loads and Prosthesis Material Properties on the Mechanics of the Proximal Femur After Total Hip Arthroplasty. Cheal EJ, Spector M, Hayes WC, J Orthop Res (in press).

[326] New Strategies for Long-Term Performance of Femoral Prosthesis

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Sponsor: VA Rehabilitation Research and Development Service (Project #A667-RA)

Purpose—The fundamental problem in hip arthroplasty with noncemented, porous-surfaced femoral prosthesis is to optimize the tissue response that follows the trauma of implantation to achieve long-term functional performance. It is important to develop procedures that would allow prostheses to remain functional for several years in active, older people as well as in younger people so that repeated revisions can be avoided. In spite of several years of research, cementless prostheses have not yet fulfilled the expectation of long-term performance. The purpose of this project is to develop new strategies to enhance long-term performance of femoral prostheses by adjuvant treatments using chitosan and microcrystalline hydroxyapatite (HA) during hip arthroplasty in an experimental model.

Methodology—The experimental model is a canine femoral prosthesis implanted in the right femur of

the dog. The methodology is designed to answer two key questions relevant to long-term performance of cementless femoral prosthesis: (1) Will some combination of osseous and fibrous tissue provide long-term mechanical and biological stability of the prosthesis-femur composite? (2) Can adjuvant therapies be employed to overcome undesirable changes in the femur that may be induced by the altered stress distribution?

Dogs implanted with the femoral component of the canine hip prosthesis are sacrificed at 1 and 6 months for evaluation of short- and long-term performance, respectively. The femur with the implant is sectioned transversely and adjacent sections are used for push-out tests, histology, and scanning electron microscopy in the backscattering mode (SEM/BES). Osseous and fibrous tissue formation within the pores of the prosthesis and around it and remodeling changes in the femur are quantified

from histology and SEM images using a computer-aided morphometry system. Standard statistical methods are used to determine correlations between mechanical and morphological data from adjacent transverse sections along the entire length of the prosthesis-femur composite. Statistical comparisons between groups (untreated controls, unoperated controls, chitosan-treated and HA-treated groups)

are done by paired analysis of transverse sections obtained from a given anatomical site.

Progress—Canine femoral prostheses have been implanted in 4 dogs. Work is in progress to finalize procedures for sectioning the femur-prosthesis composite and obtaining the morphometric and mechanical data from transverse sections as outlined above.

[327] Use of Proximal Femoral Allografts in Total Hip Revision

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Sponsor: VA Rehabilitation Research and Development Service (Project #A548-RA)

Purpose—The objective of the project is to explore *in vitro* loads at the interface between a bone graft and host bone in a total hip revision model. We want to determine the optimum construct for bone graft in proximal femoral replacement. An *in vivo* canine model will be used to demonstrate the accelerated union at the bone graft-host bone junction. The hypothesis is that a femoral component that is pressed distally with porous ingrowth in the distal end will produce a more favorable biomechanical environment to accelerate union between a proximal bone graft and the host femur. Also, the lack of distal cement would provide a better biological environment for healing of the osteotomy.

The questions to be answered to test the above hypothesis are:

- Does biological fixation increase the load at the bone graft-host bone interface?
- Does biological fixation increase initial postoperative micromotion at the interface, and does that change with time?
- Do these altered biomechanics expedite union of the bone graft-host bone junction?

We will use a canine model for a proximal femoral replacement total hip surgery. We will biomechanically evaluate load transfer and micromotion at the bone graft-host bone junction after creation of a proximal femoral replacement and either press-fit the stem distally or cement the stem into the distal femur. We will use histomorphometry

to evaluate the adequacy of bone union at the bone graft-host bone interface. This again will compare press-fit with distal cemented stem fixation.

Methodology—We have completed the *in vitro* biomechanical tests. Twenty canine femora, 10 with press-fit stems and 10 with cemented stems, were tested for load transfer and micromotion. It was found that the cemented stems were much more stable as one would expect.

The second objective was to evaluate *in vivo* the ideal proximal femoral replacements in a canine model. Twenty adult dogs had proximal femoral replacements performed, 10 with distal cementing and 10 with a press-fit distal fixation. After 4 months, all dogs will be harvested and histomorphometric evaluation of the union site and biomechanical testing of the union site will be performed. Analysis of data from the histomorphometric and biomechanical tests will be performed from Year 2 to the completion of the study in Year 3. Organization and presentation of the results will be completed in the last 6 months of Year 3.

Progress/Preliminary Results—The first phase of the project was the *in vitro* study comparing the mechanics at the allograft-host bone interface. It was found that the cemented group with distal cemented stems consistently produced the lowest absolute strain. For torsional loading the absolute strain in the cemented group was always smaller

than the press-fit group. Micromotion was much higher in the press-fit stems. We have now harvested 16 of the 20 dogs. Four of the 20 dogs had a complication. One developed sepsis 3 days postsurgery and was put down; 3 others dislocated the total hip proximal femoral replacement and were also put down. This leaves 16 dogs remaining in the study. To date, on the mechanical testing in the 16 dogs it is found that at 4 months there was no difference in the mechanical stability between a press-fit and a distally cemented stem. Histomorphometry is now being performed on the bone graft-host bone interface to see if there is any difference in bone healing between distally cement-

ing or press-fitting the stem. One change in the study was made to clarify the data. Instead of using an allograft, which would induce histocompatibility questions into the final results, it was decided to use an autograft and immerse it in liquid nitrogen to effectively kill the cells in the proximal femoral replacement. We felt this would give us much more accurate data in our study.

Overall, the data to date show that the press-fit distal stems seem to be as stable at 4 months as the cemented stems. This is a change from the *in vitro* data which showed that cemented stems had much better stability *ex vivo*. We will complete the histomorphometry over the next 4 months.

[328] Analysis of Intramedullary Implant Interface Geometry and Stability

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Sponsor: VA Rehabilitation Research and Development Service (Core Funds)

Purpose—The objectives of this study are to examine the influence of intramedullary implant-bone interface geometry on: 1) the distribution of stress through the bone; and, 2) rotational stability of the implant-bone system. The structural integrity of an intramedullary implant-bone system will depend on the distribution of stresses in the system. These stresses will, in turn, depend upon a number of factors, including applied loads, materials, and geometry. Orthopaedic procedures such as repair of long-bone segmental defects and total hip replacement involve intramedullary implants and will be sensitive to stress transfer. High-stress concentrations may lead to tissue damage and necrosis, which result in further stress concentrations in the bone or implant. Stress shielding may lead to bone resorption, which leads to stress concentrations, again throwing the system into degenerative feedback. An important aspect of stress transfer in these systems that has not been well defined is the shape of the bone-implant interface. Due to the complex geometries involved, the interface shape will also influence the relative motion of the implant-bone surfaces, a key element in the ultimate success of intramedullary implant procedures. This study evaluates the bone-implant interface, specifically focusing on the interface shape and relative motion.

Methodology—This study will utilize both experimental stress analysis and finite element modeling. The experimental analysis is divided into two parts. Part one isolates the interface shape parameter by using a phenolic composite bone analog and idealized cylindrical geometry. Part two examines rotational stability of femoral implants using cadaver femora. Finite element modeling (FEM) will be used to examine the internal and external stress and strain distribution in the idealized phenolic cylinder.

Strain gauges will be bonded to the surfaces of phenolic cylinders having machined interfaces of 0 (flat), 30, and 80 degrees. Matching steel implants will be inserted and loads applied in axial and oblique directions. Stress distributions for each cylinder will be calculated from the strain gauge measurements. Commercially available implants will be obtained and machined to have interfaces of 0, 30, and 80 degrees. Loads will be applied to the implants and relative implant-bone motion monitored using strain gauge extensometers mounted with one blade on the bone and the other on the implant. FEM results will guide strain gauge placement in the experimental model and compliment experimental results by providing a powerful means to examine load distribution at the interface.

[329] Electrochemical Testing of Galvanically Coupled Alloys Used in Total Hip Replacement Devices

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Sponsor: DePuy, Inc.

Purpose—Past electrochemical testing of orthopaedic alloys (Ti-6Al-4V and Co-Cr-Mo) has indicated that the rule against mixing metals can be waived based upon the extensive passive region of both materials in the vicinity of *in vivo* corrosion potentials. Based on this finding, total hip replacement (THR) designs combining these materials in a nominally optimal way have been developed which have a Co-Cr-Mo ball fitted into a Ti-6Al-4V stem. Such designs have recently been introduced into clinical practice. Retrieval studies, however, are turning up situations of extensive surface attack of usually passive materials.

Possible reasons for the discrepancy between behavior predicted from research data and that observed clinically are that the data are not directly applicable to the clinical situation because they do not consider that passive films can be intermittently abraded by frictional loading, they were not taken over time scales for which these phenomena manifest themselves clinically, or did not account for crevice conditions such as could exist at the ball component/stem junction. The experimental program described below attempts to systematically determine the reason(s) for the unexpected lack of *in vivo* corrosion resistance of these new THR devices.

Methodology—A long-term three-stage study of corrosion of these materials is being undertaken to assess the relative contributions of galvanic coupling, crevice corrosion conditions including design factors, and applied loading to the surface attack.

Except for the polarization curve measurements mentioned below, the corrosion tests will be nondestructive and will be repetitively performed sequentially in time. These will include measurement of corrosion potentials and linear polarization and AC impedance measurements.

Ringer's solution will be used for the testing program. Because of the possibility of a 12-18 month incubation time associated with this corro-

sion phenomenon, an elevated temperature will be used. This should lead to more rapid initiation of surface attack.

The test specimens will be fabricated from the alloys and metallurgical conditions which reflect present implant practice. For the specimens in which there is galvanic contact between the two alloys and crevices, the areas of the various portions of the samples will be chosen to scale to situations which realistically duplicate *in vivo* conditions.

The phase I of the testing program, the influence of galvanic coupling will be examined by studying the corrosion behavior over time of five discrete electrochemical test conditions: 1) isolated specimens of each alloy; 2) active surfaces of isolated specimens of each alloy; 3) galvanic coupling; 4) galvanic coupling of active surfaces of each alloy; and, 5) potentiodynamic polarization curves taken at sequential intervals.

In phase II, a situation involving galvanic coupling plus crevice corrosion will be examined. In this aspect of the work, tests will electrochemical conditions 3 and 4 listed above will be performed on specimen groups in which crevice corrosion conditions are created artificially. The specimen designs and electrochemical cells will be such that the chemistry in the crevice will be appropriately simulated.

Phase III will deal with the influence of applied loading and design. The approach will be to use specimens of simple geometry which simulate a range of conditions of mismatch of the stem/head taper angle. For these tests, sinusoidal load will be used. Since, as previously noted, incubation times for this corrosion failure type can range over a year, it is not feasible to employ 1 Hz loading. To get around this constraint, it is planned to employ one million loading cycles at 10 Hz. This will simulate approximately one year's worth of loading in 11.5 days. An elevated temperature electrolyte will be used here also.

[330] Force- and Pressure-Sensing Endoprosthesis

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Sponsor: National Institutes of Health

Purpose/Methodology—*In vivo* pressure measurements in the human hip during certain maneuvers ranged to as much as twice as high as those obtained during prior *in vitro* studies. *In vitro*, the pressure-instrumented pseudo-endoprosthesis was loaded into cadaver acetabuli and subjected to forces reported in the literature as the forces experienced at the hip *in life*. Subsequent myoelectric data, synchronized with the pressure data, indicated significant levels of co-contraction of agonist and antagonist muscles across the hip.

The only confident determination of the actual forces the hip experiences *in life* will come from direct measurements. Prior attempts to obtain such measurements have been frustrated by device failures early after implantations, complex calibration routines, and the use of total hip replacement prostheses, which do not replicate the natural anatomy of the replaced skeletal structures.

To settle the issue of hip force *in life*, we have redesigned the pressure-only instrumented endoprosthesis to also accommodate a force-and-moment transducer system in the hollow femoral neck portion of the prosthesis. The proven-reliable electronic telemetry system has been expanded to 32 channels to permit transmission of the new data along with the data from the 14 pressure transducers that will be retained in the load-bearing femoral

head. Temperature close to the interarticular surface will also be measured.

Progress—Negotiations with an orthopaedic appliance manufacturer have converged on the geometry and materials of the stem and hemisphere portions. Unavoidable material changes from the original design analysis and verification will necessitate reevaluation of the finite element modeling analysis and further physical testing, both for determination of the patient safety assurance and to determine the sensitivity of the strain-gauged hollow neck portion.

Future Plans—Following completion and implantation of the device and rehabilitation of the patient, extensive studies will be conducted with pressure, force, moment, and temperature data acquisition from the prosthesis simultaneous with the kinematic and kinetic data stream from the TRACK system. Comparison of the inverse Newtonian analysis force estimates from TRACK data with the direct force measurements will quantify the extent of muscular co-contraction occurring across the hip joint. These data can then be employed in lower extremity musculoskeletal models to generate improved estimates of the force level in, and time course of, individual muscles participating in the movement.

[331] Synovial Joint Biomechanics and the Pathogenesis of Osteoarthritis

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Sponsor: Whitaker Foundation, Whitaker Professorship of Biomedical Engineering, Newman Laboratory Fund

Purpose—Osteoarthritis, or degenerative arthritis, disables more Americans than any other disease, producing much pain and loss of mobility while causing the greatest loss of worker productivity. This project is exploring how the human hip joint accommodates the forces and displacements of normal movement, and whether (and if so, how),

these mechanical factors contribute to the pathogenesis of osteoarthritis, either directly or by affecting the biology of cartilage.

Methodology—The *in vitro* phase of the investigation involved analysis and experiment on human hips from cadavers and the development of a

detailed mathematical model of the cartilage and bone in this ball-and-socket synovial joint. Results include interarticular surface stress and strain, fluid exuded/imbibed, fluid pressures and the interarticular flow paths, solid matrix friction, entropy generation, and consequent temperature rise.

The *in vivo* phase includes five years of unique pressure data from the human hip. We now also have the unique opportunity to study *in vitro* the acetabulum and the pressure-instrumented endoprosthesis from which we acquired our five years of *in vivo* data. We plan to both replicate *in vivo* experiments and perform tests not feasible in life.

Results—Computer simulations of the human hip synovial joint and correlating experimental data confirm the role of the interarticular seal in maintaining the high fluid pressures which, for a healthy joint, carry typically more than 90% of the load. The degeneration of this seal is, we believe, tantamount to osteoarthritis. Accordingly, we are focusing on understanding the nature of this remarkable resistance to fluid flow. The cartilage-to-cartilage spacing in synovial joints *in life* is thought to be very small, but has never been measured.

[332] Correlation of In Vivo Synovial Joint Pressure Data With That From Posthumous Hemipelvis and Proximal Femur Including Pressure-Instrumented Endoprosthesis

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Sponsor: Whitaker Health Sciences Fund

Purpose—Only one pressure-instrumented femoral head prosthesis has ever been implanted: after five years as an effective joint and source of unique data, that prosthesis was retrieved posthumously, together with the proximal femur and hemipelvis. Extensive *in vivo* data acquired during a broad spectrum of physical activities are being compared with *in vitro* data taken during experiments in the laboratory which replicate the circumstances during life. Such *in vitro* experiments permit control over experimental conditions which was not possible *in vivo*, and which will contribute to further interpretation of the *in vivo* data. Geometric evaluation of the acetabular cartilage following five years of contact

A feasibility study of a technique to measure the interarticular gap using ultrasound was performed. Theoretical analyses for the experiments, the instrumentation, digital signal processing algorithms, and experimental techniques, were developed and applied to the measuring technique with encouraging results. Subsequently, ultrasonic instrumentation was installed in a pseudo femoral-head prosthesis, opposed to cadaver acetabuli, in order to measure *in vitro* the global distribution of clearance between the prosthesis and the natural cartilage of the pelvis of the hip joint. The resulting measurements were consistent with prior modeling studies which indicate that the interarticular gap is very small, characterized geometrically by small-scale irregularities superimposed on the spherical cartilage surface. Most of the applied load on the joint is carried by fluid pressure extending throughout the cartilage with perhaps no more of the apparent contact area being solid-to-solid contact.

Recent Publications Resulting from This Research

Characterization of the Interarticular Gap in the Loaded Human Hip Joint. Qiang X, PhD diss., Massachusetts Institute of Technology, 1991.

with a well-matched femoral head replacement also provides information never previously obtained, which is relevant to the longevity of this commonplace orthopaedic procedure.

Methodology—Apparatus for high-pressure calibration of pressure sensors in the retrieved prosthesis and software on a personal computer for acquisition of data were applied in the recalibration, including the effect of temperature on pressure sensor output. Ultrasonic geometry measurements on the excised acetabulum were completed. Static tests in the Hip Simulator, a multi-axis, electrohydraulic testing facility, were commenced to be followed by dynamic

experiments with the Hip Simulator under computer control.

Results—The calibration of the pressure transducers in the retrieved prosthesis were very similar to comparable data generated prior to implantation over six years ago. The linearity of the transducer design was confirmed by extending the pressure range from the 8 MPa maximum originally expected to the 18 MPa value experienced in life. The ultrasonic geometric measurements of the acetabular cartilage verified that the general geometry conformed identically to the prosthesis femoral head. However, the cartilage thickness had thinned considerably, with some areas below the minimum resolution of the technique. This finding and the *in vitro* pressures, which corresponded to those acquired *in*

vivo, were consistent with a progressive consolidation and protrusion of the head into the cartilage over the 5-year span of contact.

Future Plans/Implications—Correlation of *in vivo* and posthumous *in vitro* pressure data will contribute to the confident quantification of the forces experienced at the hip joint in life. This information and the geometric acetabular measurements are expected to influence the design of femoral head replacements and surgical procedures, both involving hemiprosthesis and total joint replacement.

Recent Publications Resulting from This Research

Postmortem Cartilage Changes Due to *In Vivo* Hip Pressures. Clayton MC, et al., in Proceedings of the 38th Annual Meeting of the Orthopaedic Research Society, Washington, DC, 1992.

C. Knee

[333] Articular Cartilage Replacement Prosthesis for the War-Injured and Aging

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Sponsor: VA Rehabilitation Research and Development Service (Project #A424-RA)

Purpose—Left untreated, focal defects in articular cartilage produced by excessive joint loading can grow to the extent that they lead to degeneration of the entire joint, and the need for total joint replacement. The objective of this investigation is to develop a prosthesis that can replace these focal defects in articular cartilage. In its initial form this prosthesis would be a cylindrical implant inserted into holes drilled through the articular cartilage defects. The device would have a polymeric surface that would be capable of articulating against the apposing natural articular cartilage without causing accelerated degeneration of that or surrounding tissue.

Methodology—One task is to investigate the mechanical properties and tribology of candidate materials to be employed for the articulating surface of the device. The compressive compliance of the

candidate elastomers is being evaluated for comparison with natural articular cartilage. In a tribological apparatus, natural articular cartilage specimens are being rubbed against candidate polymeric substances. The coefficient of friction and the degradation changes of the articular cartilage are being determined.

The materials evaluated in this study were biomedical-grade polyurethanes. The materials were obtained in pellet form, dried, dissolved in solvent (THF or DMAC), and solution cast on glass plates. The solvent and concentration were varied until the resulting films ranged from 1 to 2 mm in thickness. Compliance measurements were made using an Instron model 1331 closed loop servohydraulic universal test machine equipped with a 100 lb load cell and a PC-based data acquisition system. Indentation tests were conducted in stroke control at a rate of 0.05 mm/sec using a 1.6 mm hemispherical

indenter. The maximum displacement was 0.5 mm. Data acquisition was performed at 100 Hz. Fresh bovine articular cartilage was tested in an identical fashion to serve as a positive control. Ultrahigh-molecular-weight polyethylene served as a negative control. The compliance was computed from the slope of the load-displacement data using a least-squares, best-fit technique.

Coefficient of friction measurements were made using a pin-on-disk wear machine (Implant Sciences Corp.) equipped with a force transducer and a PC-based data acquisition system. Four-millimeter diameter plugs of fresh bovine articular cartilage were used as the pin material. Testing was conducted at a sliding speed of 25 mm/sec, with a nominal contact stress of 0.4 MPa and with distilled water used as a lubricant. Counter face materials included polyurethane film, ultrahigh-molecular-weight polyethylene, alumina ceramic, and a cobalt-chromium alloy. After testing, the articular cartilage plugs were examined for signs of wear. Representative samples were processed for scanning electron

microscopy evaluation, while other samples were processed for histologic evaluation.

Progress—The compliance results Tecoflex® SG-80 and SG-85 materials were comparable to the compliance of articular cartilage under the conditions of our testing. Dynamic mechanical property measurements are in progress to determine the time-dependent behavior of the polymer materials and articular cartilage. Wear testing is in progress. The results of tribological evaluation for the Tecoflex SG-85/articular cartilage couple indicate that the coefficient of friction for this material combination is very low ($COF = 0.04$) with no damage visible on preliminary examination. Histological and SEM analysis is in progress.

An animal model has been developed to evaluate the efficacy of the articular cartilage replacement prosthesis (ACRP). Cylindrical holes drilled in the patella of dogs are serving as the test sites in which to evaluate the performance of candidate ACRP constructs and autograft controls.

[334] All-Plastic Total Knee Replacement

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Sponsor: VA Rehabilitation Research and Development Service (Project #A217-3RS)

Purpose—Potential problems with currently available metallic total joint replacement prostheses relate to the high stiffness of the device that leads to greatly altered distribution of strain in surrounding bone. This can lead to a net decrease in bone density as a result of the adaptive bone remodeling in some areas around the device. A second concern relates to the adverse biological response that might be elicited by metal ions released from the device. The overall goal of this project is to develop a total knee replacement made entirely from polymeric material (including fiber-reinforced polymeric composites). A specific objective is to test the hypothesis that a more compliant polymeric total knee replacement prosthesis leads to more physiological remodeling of underlying bone.

Methodology—One objective of this phase of the study was to develop a finite element model for

structural analysis of the canine distal femur. This model will be used to predict the stresses in the bone supporting the femoral component of a total knee arthroplasty for the evaluation of various implant materials. The intact femur will also be analyzed to provide reference data. The predicted stresses will be compared directly to the measured bone remodeling in the animal studies. This comparison will test our hypothesis that a femoral component of lower modulus materials can reduce the bone resorption that results from adaptive remodeling in comparison to that seen with conventional metallic components.

A second objective of this phase of the investigation was to determine the bone density around the femoral component of total knee arthroplasty using computerized tomography (CT). The fixation and stability of the femoral component of a total knee replacement is dependent on the quality of the supporting bone. Our hypothesis is that the best

design is directly supported by the greatest proportion of high-density trabecular bone. The task was to evaluate various designs for the femoral component by measuring the distribution of trabecular bone density in the human distal femur relative to surface geometry of the component.

Progress—A three-dimensional finite element model was generated of the distal femur of a Labrador-type dog weighing approximately 35 kg. The geometry of the model was digitized from direct sections of the femur. The material properties were determined using CT scans and custom software. Linear orthotropic material properties were assumed for the cortical bone. Linear isotropic material properties were assumed for both the trabecular bone and the cortical shell when the thickness of the shell was less than 2 mm.

Due to the lack of published data on the loads in the canine knee, we assumed that femoral contact loads in the dog were similar to the femoral contact loads in the human, scaled to body weight. The size and location of the contact area of the patellofemoral joint were based on literature data. The size and location of the contact area of the tibiofemoral joint was determined by medial and lateral photographs of the excised canine knee at 30, 60, 90, 110, and 130 degree angles of flexion.

The three-dimensional finite element model is in the final stages of preparation. The model of the intact distal femur will be analyzed first. The operated knee with the surface replacement component will then be modeled by changing the material properties of the appropriate elements at the articular surface. Separate analyses will be performed for

cobalt chromium, titanium alloy, and carbon fiber-reinforced composite materials.

CT scans were made of two human cadaver femora. The scans were taken at a spacing of 3 mm, perpendicular to the long axis of the femur. A phantom was included in the scans to calibrate each image and thus convert the CT density to bone apparent density. Volume rendering software on a Sun workstation was used to produce a three-dimensional reconstruction of each femur from the CT images. Three two-dimensional medial-lateral sections were then made from each three-dimensional data set. These sections were centered in the medial and lateral condyles and the intercondylar notch of the distal femur. A rectangular grid was then placed on each of these two-dimensional images and the average bone densities were determined for each square region of the grid.

Two different peg locations were investigated for the section through the medial condyl (peg 1— anterior; peg 2—posterior). The implant was superimposed on the grid to determine the density of the bone surrounding the implant for each of the two possible peg locations. The grid elements adjacent to the implant surface were averaged to determine the density of bone in contact to the implant. The mean density of the bone at each peg location was also calculated. The bone density was somewhat higher for the more posterior peg location (peg 2). The lowest bone density (0.37 gm/cc) occurred between the two peg locations. The density of bone at the peg location (the bone lost by insertion of the device) was also slightly higher for the more posterior peg location.

[335] Improved Anchorage of Knee Replacement Based on Confirmed Design Rules

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Sponsor: VA Rehabilitation Research and Development Service (Project #A546-RA)

Purpose—There is a need for excellent long-term fixation of tibial components of total knee implants. The purpose of the project is to develop a tibial

component that will not exhibit the same level of loosening seen in either cemented or noncemented porous coated implants.

Progress—To date, 16 implants have been manufactured. Six of these have been implanted in acute, nonsurvival or short-term survival dogs. This experience led to significant improvement in the design of guide wires and templates. Four implants have been implanted in survival dogs for periods of 2 to 3 months. These dogs have been subject to a daily exercise program and bimonthly radiographs of the implants.

Methodology—Hinged knee joints were implanted in the right knees of dogs. To insert the implants, part of the tibial tray and the femoral condyles had to be resected. The femoral component was cemented in while the threaded tibial peg was inserted as a press-fit for osseointegration. The dogs were exercised daily, 5 miles, with a 2 lb weight around the thigh on the operated side.

Results—In all dogs except one there were progressive radiolucencies around the tibial pegs. The dogs

with radiological implant loosening appeared to suffer from locking of the knee joint in either extension or partial flexion. Accordingly, it appears that the hinge is the weak part of the design. The four survival dogs were sacrificed, and the tibias containing the tibial pegs subject to torsional testing in order to evaluate strength of fixation. As a control, a tibial peg was implanted in a fresh cadaver tibia giving intimate bone-implant contact. Torsion tests revealed that the three cases of radiologic loosening also were completely loose mechanically. The strength of fixation of the one successful implant was comparable to that of control specimen. Thus, the preliminary conclusions from this project are that the hinge needs to be redesigned according to low-friction concepts before the last six implants are implanted. Only then can the tibial peg be subject to the continuous cyclic loading required for successful osseointegration.

[336] Composite Grafts for the Repair of Cartilage Lesions

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Sponsor: VA Rehabilitation Research and Development Unit (Core Funds)

Purpose—The purpose of this research is to investigate a new approach for the repair of articular cartilage lesions. The long-term objective of this project is to provide a viable composite articular graft with biomechanical and structural properties compatible with those of normal articular cartilage.

Progress—The pilot study began in June 1991, and the investigators have held several meetings to define the methods and approaches to address these issues.

Methodology—The following questions will be addressed:

- Do chondrocytes plated on a synthetic degradable substrate continue to express chondrocyte phenotype?
- Do synthesized proteoglycans reconstitute extracellular matrix architecture?
- How do chondrocytes populate a three-dimensional substrate and arrange the newly synthesized extracellular matrix?

- How does the new extracellular matrix alter the biomechanical properties of the substrate and how does this approach the properties of normal articular cartilage?
- Does the repopulated degradable substrate become physiologically incorporated into the articular surface *in vivo*?
- How does the presence of the composite graft affect long-term conditions of the joint?

This project is divided into two steps: the first step involves the *in vitro* study of cultured chondrocytes in polymeric porous and fibrous scaffolds (HDPE and synthetic collagen) with specific architectures. The second step consists of evaluating the performance of these composite grafts (chondrocytes seeded in collagen scaffold) in conditions using the lapin femoral condyle as implantation site.

Medical-grade HDPE powder was screened in three sizes: 40 μm , 200 μm , and 400 μm . Each

powder was sintered at 100° C in hot isostatic pressure conditions to obtain an average 50–65% porosity. Using scanning electron microscopy, the pore size range for the 40 μm powder varied from 20 to 40 μm and 150–300 μm for the 200 μm beads. Pores of 350–500 μm were observed for the 200 μm powder. Cylindrical plugs (2 to 3 mm thick \times 10 mm in diameter) were cut into the porous films. Fibrous structures were made with extruded fibers (50–100 μm in diameter) of HDPE which are knitted, woven, or hooked in a knitted base by looping (such as in Velcro™). Cylindrical plugs (2 to 3 mm thick \times 10 mm in diameter) were also fabricated. Six types of structure will be studied: porous (3 types of pore) and fibrous structures (3 types of structure).

Different parameters of importance for tissue ingrowth will be characterized for each porous structure. These parameters are: pore (or voids) size, pore volume, porosity, pore interconnection. Scanning electron microscopy and a non-contact profilometer (TOPO-3D™ by Wyko Corporation, AZ) will be used to observe and quantify the overall surface architecture of the substrates. Also, the

viscoelastic behavior of the scaffolds under compressive loading will be characterized using a nominal contact stress of 4 MPa (in the range of normal physiological joint stresses).

Bovine chondrocytes (six million cells) will be suspended in the porous structures. After 1 month, the plugs will be tested for proteoglycan synthesis, collagen formation, mechanical properties, and DNA. The structure offering optimum biochemical and mechanical properties will be made of synthetic collagen. Collagen plugs with the optimum architecture will be seeded with lapin chondrocytes using the protocol described above, and cultured for 21 days. The collagen composite grafts will be implanted in osteochondral defects in the right medial femoral condyles of mature rabbits. The left medial condyle will be used as a control and filled with a scaffold of collagen without chondrocytes. The grafts will be implanted for periods of 1, 3, 6, and 12 months (six animals in each group). After sacrifice, the knees will be harvested, mechanically tested (indentation tests), and subsequently prepared for TEM, SEM, or optic microscopy.

D. Spinal

[337] Predisposing Factors in Disc Prolapse

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Sponsor: VA Rehabilitation Research and Development Service (Project #A627-RA)

Purpose—This 3-year study will work toward identifying predisposing factors in disc prolapse. This will be accomplished by mechanically testing intervertebral discs and then examining them using histological and biochemical methods. This study will provide key information relating a disc's inability to withstand mechanical loads to the composition and tissue distribution of the proteoglycans.

The project is to "window-in" at a specific time in life of the disc. The information obtained will be extrapolated backward to understand why some discs have reached the stage where they have a propensity to prolapse.

Progress/Methodology—The process to recover cadaveric spines has been initiated. Each year for 3 years, approximately 40 lumbar spines will be retrieved from fresh cadavers. From this number of spines, approximately 300 discs will be obtained for study. For each disc, the processing involves mechanical testing, recovering of the histological and biochemical samples, and conducting the histological and biochemical analyses. It is deemed necessary to test 300 discs in order to cover the age spectrum and to allow us to focus on particular features. These data will be compiled in a matrix format and analyzed by correlational methods. It is expected

that this approach will yield significant correlations between the distribution of proteoglycans, which reflects the stage of disc function, and the absolute

amount of proteoglycans. These data will reflect upon the relationship between proteoglycans and the disc's load-bearing capabilities.

XII. Orthotics

[338] Development of High Strength/High Modulus Thermoformable Splint and Brace Materials

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Sponsor: *VA Rehabilitation Research and Development Unit (Core Funds)*

Purpose—The purpose of this research is to develop and evaluate the mechanical behavior and use of thermoformable fiber reinforced polymer splint and brace materials. Nonreinforced thermoformable splint and brace materials are currently used in orthotic applications requiring low strength and low stiffness. In situations requiring higher strength and stiffness, glass fiber/thermoset matrix composite materials are typically used. These materials, however, cannot be reshaped once formed and therefore must be discarded and refabricated if shape corrections are necessary. Thermoformable fiber reinforced splint and brace materials will provide the strength and stiffness of the presently used fiberglass splint and brace materials while allowing corrections and adjustments in splint and brace position to be made at any time by the application of low-level heat.

Progress—A multicenter research program is being planned aimed at the development and evaluation of high strength/high modulus thermoformable splint and brace materials.

Methodology—The initial phase of this research will involve feasibility studies into the fabrication of thermoformable fiber reinforced polymer prepreg materials. Laminates will be produced from several fiber/polymer material combinations and evaluated in terms of thermoformability, mechanical properties, and their potential for splint and brace applications. From the results of this short-term feasibility

study, a 3-year research program for the development and evaluation of the most promising materials will be planned. This project will involve the collaboration of research teams at Clemson University, Emory University, and Simula, Inc. Clemson University researchers will be responsible for materials fabrication and finite element modelling to design and evaluate multidirectional laminates in splint and brace applications. Emory University researchers will investigate specific splint and brace applications for these new materials, and define the biomechanics involved in these specific applications. Once multidirectional laminates are fabricated, Emory researchers will then be responsible for splint and brace materials evaluation in simulated clinical use and comparison of the new material to the performance of materials currently available. Simula, Inc. researchers will be responsible for the mechanical testing of the unidirectional laminates and for providing this mechanical data to Clemson University for use in the finite element model for multidirectional laminate design. Simula, Inc. will also mechanically test the multidirectional laminates following their design and fabrication.

Implications—The successful completion of this research program will potentially lead to the development of thermoformable high strength/high modulus splint and brace materials for clinical use that are superior to presently available materials in terms of both patient care and overall treatment cost.

[339] Adjusted Versus Unadjusted Foot Orthoses in the Prevention of Foot Ulcers in Diabetics

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Sponsor: VA Rehabilitation Research and Development Service (Project #A607-RA)

Purpose—This study will help determine if custom in-shoe orthoses will alter distribution of plantar foot pressure by measuring their effects upon stance phase foot deformities. Determinations will also be made, using the same parameters, whether adjustments are necessary as foot orthoses are worn and, in diabetic patients who have previously ulcerated

their feet, whether adjusted custom foot orthoses decrease the incidence of re-ulceration.

Progress—Nine patients were enrolled before the new software arrived. After the software (which allows bipedal recording) was received, more subjects were enrolled into the 18-month study.

[340] Clinical Evaluation of the Vannini-Rizzoli Stabilizing Limb Orthosis

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Sponsor: VA Rehabilitation Research and Development Service (Project #B597-EA)

Purpose—The purpose of this project is to evaluate the Vannini-Rizzoli Stabilizing Limb Orthosis (VRSLO) as a means to permit standing and ambulation with a minimal expenditure of energy, in spinal cord injury (SCI) patients with paraplegia or paraparesis due to lesions of the cord.

Also included in the study is the establishment of the appropriate criteria for candidate selection, alteration of the treatment plans for those selected, selection of proper exercises, possible contraindications and/or precautions, establishment of the duration of the client's program, and incorporation of this information into the clinical application of the VRSLO or, as it is commonly referred to, "The Boot."

Methodology—The VRSLO is a carefully configured brace that is inserted into a leather boot and used to aid ambulation of individuals with lower extremity dysfunction. Use of the Boots causes a 10–15° plantar flexion of the foot and stabilization of the ankle; the patient stands with hips thrust forward causing locking of knees and hyper-

extension of the back, resulting in a stable stance. When proper weight-shifting techniques are combined with stance, the person may ambulate with a pendular motion of the unweighted limb and an assistive device (e.g., walker, quad canes) for support. SCIs ranging from C6 to L3 have been fitted, but ambulation status obviously differs from person to person.

Patients chosen to participate in this project must meet the following criteria:

1. Have full passive/active range of motion (ROM) and stability in all joints of the lower extremities;
2. Upper extremities must be functional with normal muscle strength to support upper body weight when ambulating to prevent falls;
3. Must be able to pull oneself to a standing position independently;
4. Must be able to develop a tolerance for standing;
5. Must be in good physical condition with no cardiovascular history;
6. Must be able to adjust to spasticity;
7. Must have a firm commitment to participate.

When selecting patients, precautions such as low back pain, severe scoliosis, and Harrington rods for spinal stabilization must be taken into consideration but should not be used as contraindications.

The Boot Program has three main stages: pre-exercise program, measuring/fitting, and post-exercise program. The pre-exercise program consists of exercises designed to teach individuals how to use their upper bodies to achieve reciprocal movements to the lower extremities. This stage lasts 3–4 hours per day for 3–5 weeks. Toward the end of the pre-exercise stage, individuals are measured and fitted for their Boots, which are fabricated in Italy and delivered to the rehabilitation center for final fitting and user training. When the Boots arrive, the individual starts his/her postexercise program, shifting emphasis from mat exercises to standing/ambulation training. The postexercise program involves standing-balance exercises and progressive ambulation training starting in the parallel bars, progressing to a walker or quad canes. The exercise program lasts 3–8 weeks, depending on the progress of the individual patient and his or her level of injury.

Further refinement of skills may incorporate stair climbing, ramp walking, and car transfers.

Progress/Preliminary Results—*James A. Haley Veterans Hospital, Tampa, FL.* The Tampa VA Hospital, which was the site of the original pilot study for the Vannini-Rizzoli Boot, has presently stopped taking new patients. Over the last 2 years, 65 patients were evaluated and 30 accepted to our program. Ages range from 19 to 60 years old with length of injury from 6 months to 38 years. Levels of injury range from C7 complete quadriplegia to L2 paraplegia.

The VRSLO has been very successful. Patients are ambulating from 60 to more than 1,000 feet using a rolling walker or quad canes for a success rate of 80%. Some patients are capable of negotiating ramps and stairs. Ten patients are still active in the program and should finish in 8–10 weeks.

This new orthosis has increased independence, allowing patients who have been in wheelchairs for as much as 38 years to ambulate independently in their homes and for moderate distances outside of their homes. It has eliminated the need for some patients to make structural changes to their homes since they can ambulate independently. Several

patients have stated that they have not had a urinary tract infection since using the Boots. Others have stated they do not need to seek out a wheelchair-accessible hotel when on the road. These are just several advantages the Boot has given our patients.

VA Medical Center, San Diego, CA. The VA Medical Center, San Diego joined the evaluation team for the VRSLO in July, 1990. Eighteen patients were selected to participate in the study, utilizing the selection criteria established by the Rehabilitation Research and Development Service, VA Central Office.

Patients ages ranged from 21–62 years old. Sixteen patients were paraplegic (T6 and below); nine complete and seven incomplete. (There was one patient with central cord syndrome, and one C7 complete injury included.) Of these 16, 9 are ambulating with walkers, 2 are ambulating with Loffstrand crutches, and 1 is ambulating independently, with canes. Two paraplegics who were ambulating with bilateral KAFOs prior to the Boot program, returned to the long leg braces because they felt the braces provided more stability. Two patients withdrew from the study because of the time and energy commitment required, but intend to return later. One patient was discharged. One paraplegic patient is still in the preprosthetic training program since multiple medical complications unrelated to the Boot program delayed his progress. Of the two quadriplegic patients, the C7-complete is ambulating with a walker for short distances with supervision and the patient with central cord syndrome has advanced to bilateral AFOs.

Although our evaluation did not include oxygen and energy consumption studies, it has seemed that the process of standing up required extreme effort. When we applied FES to bilateral hip and knee extensors to assist patients rising from the sitting position, it significantly decreased the apparent energy requirement. We are planning to continue utilizing the Boots for ambulation. Application of FES to assist standing up improves patient compliance, eliminating the extraordinary effort they have to exert for this activity utilizing upper extremity muscles.

Our overall experience was that the Boot program not only provided an excellent exercise program and improved functional levels of activity, but also had a great impact on self image. Most patients who graduated from the program had a new or enhanced outlook on life.

Edward Hines Jr., VA Hospital, Hines, IL. The Hines experience has met with some success as our techniques for recruitment and training were further refined. Of 22 participants utilizing the Boots, 11 persons achieved functional status and we feel others might have enjoyed greater use had participation been sustained. One femur fracture occurred (in addition to the tibial plateau fractures reported last year), but good healing followed. Interestingly, our functional users included levels as high as C8-T1, as well as paraplegics T5 and lower.

The overall impression is that the orthosis is a viable method for mobilization following SCI and that a devoted team effort is as important as the patient's strong desire to be ambulatory.

Brockton/West Roxbury VA Medical Center, West Roxbury Division, West Roxbury, MA. Forty-four paraplegics and quadriplegics have been evaluated; 27 met the criteria for entry and 10 have completed the study. Of the 10, 7 have reached significant levels of ambulation and 3 have returned the VRSLO. There were eight initial ambulators; all were able to walk in the parallel bars within 1 or 2 days after receiving the Boots. All seven successful ambulators are able to ascend and descend stairs; six are limited community-level ambulators and one is at the household level. Three of the seven ambulators have been functional for over 1 year, and four have been functional for from 1 to 10 months.

Two of the three who are not using the Boots did not achieve the standing position due to limited ROM and/or inability to control spasticity. Although the third participant was a limited community ambulator, he preferred using his wheelchair. Two out of those three who returned Boots are wheelchair athletes.

Seven of the nine completed candidates who previously used conventional braces, report the Boot to be easier to put on and take off than the braces. The other two report little or no difference. Five of the seven feel the Boot is more cosmetically acceptable than the braces. Two failures and two successfuls state the Boot is less cosmetically acceptable than the braces.

The 17 yet to complete the study have experienced various limiting factors. Two are ambulating with walkers; although they are independent, they are not functional due to the large amount of energy expended in walking short distances. Five are stand-

ing independently, but are limited by spasticity and failure to complete the pre-orthotic program. Ten have not yet advanced to weightbearing in the Boots: three have completed the pre-orthotic program, three have limited time to devote to the study resulting in limited ROM in knees or hips, one has not completed the postorthotic program, one suffered a tibial fracture during an independent home exercise program, one has had cellulitis in the lower leg, and one has increased spasticity which is not yet controlled.

Two participants have a spinal fusion and two had a stabilizing device in the spine which was removed several years prior to the study. Two participants still have a stabilizing device, one of whom has returned the orthosis.

VA Medical Center, Bronx, NY. The VRSLO program has continued at the Bronx VA Medical Center. A total of 21 pairs of Boots have been used (18 for the patients selected at the onset of the study, and 3 subsequent orders).

Eleven patients have had their Boots released to them for their use. Four pairs of Boots have been released to other pilot study centers. Six pairs of Boots are being held for possible future use. One patient uses his Boots almost all the time (Summer). Two patients use their Boots occasionally. The others wear them very rarely, or not at all.

Sakina Foster, KT, and Renard Johnson, KT, continue to evaluate potential candidates and are scheduled to see two additional patients.

Hunter Holmes McGuire Medical Center, Richmond, VA. Twenty candidates ranging in age from 20 to 42 years were evaluated for the program. Eleven paraplegics and one quadriplegic (incomplete) met the criteria, and orthoses were ordered. Five subjects have completed the program; four of these veterans have ambulated at home or at a limited community level since May 1, walking distances of 150-400 feet, while the fifth candidate did not achieve safe, independent ambulation. Two of these users are able to negotiate stairs. Three of the four ambulators were prior users of conventional long leg braces, and all report the Boot to be lighter in weight, easier to don and doff, and more cosmetically acceptable. One subject withdrew from the study for personal reasons and another is currently engaged in postorthotic training (ambulating 40 feet in the parallel bars with assistance). The remaining five subjects are awaiting arrival of

their orthoses. The results of the evaluations will be forwarded directly to the VA Prosthetics Assessment

and Information Center, Rehabilitation Research and Development Service in Baltimore, MD.

[341] Orthotic Stabilization of Thoracolumbar Injuries

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Sponsor: VA Rehabilitation Research and Development Service (Project #A509-RA)

Purpose—Spinal orthoses have traditionally played an important role in the early mobilization of patients with thoracolumbar injuries. However, the treatment protocol for orthotic management of spinal fractures remains subjective due to a lack of objective data defining the three-dimensional (3-D) instability of spinal fractures and the extent to which different spinal orthoses can improve the biomechanical stability of the injured spine. The objective of this study is to evaluate the effectiveness of spinal orthoses in controlling the progression of deformities at the injured segments under the action of different loads and for different injuries.

Progress/Methodology—A finite element model (FEM) of the ligamentous spine with ribcage was used to investigate the effectiveness of the Jewett hyperextension orthosis. The model consisted of 17 beam elements, and the interaction of a Jewett orthosis with the spine was simulated using experimentally measured stiffness properties of the brace. The model was used to predict displacements at the injured segment and loads exerted by the orthosis on the trunk.

We have extended the above model by incorporating the detailed anatomical structures of the thoracolumbar region T11-T12-L1 based on the geometry of a cadaveric specimen and material properties from the literature. The detailed model of the thoracolumbar region is incorporated into a simpler beam-type representation of the remaining segments of the trunk, including the ribs. This will allow us to simulate the damage to individual anatomical components associated with each type of injury, and thus, will facilitate clinical interpretation of model results. The detailed model has been used so far to study the stress patterns arising in the

thoracolumbar spine during the production of burst fracture.

A comprehensive experimental protocol to study the biomechanical function of three-point hyperextension spinal orthoses has been developed and carried out on seven healthy male subjects. The subjects performed various trunk range-of-motion tasks as well as trunk lifting efforts, first without wearing an orthosis, and then while wearing the Jewett and the Cash orthoses. The orthoses were instrumented with force sensing resistors, and trunk muscle electromyographic (EMG) activity, *body segment position data*, and external reaction force data were recorded. Initial results show that both of the orthoses tested applied extension moments to the trunk upon initial fitting of the orthoses, and that the orthoses-applied moment increased as the subjects flexed forward and increased even further as the subjects performed static isometric trunk extension efforts in the same flexed posture. The ability of these orthoses-applied moments to unload the spine is currently being investigated by analyzing the EMG data.

In the third component of the project, we have completed an *in vitro* investigation of the surgical stabilization methods for the L1 burst fracture. The 3-D load-displacement characteristics of the T12-L2 segment were measured using an optoelectronic (WATSMART) system in the intact mode, following experimentally produced burst fracture of L1, and following sequential stabilization of T12-L2 with three pedicular screw-plate systems (Luque plate, VSP, and ISOLA). Results of the 3-D instability patterns of the burst fracture are reported by Slosar, et al. The instrumentation data are currently being analyzed.

Future Plans—The experimental data gathered in the *in vitro* and *in vivo* studies described above will

serve as input to the finite element model to investigate response of orthotically supported injured spine to loads in three planes.

Recent Publications Resulting from This Research

Orthotic Stabilization of Thoracolumbar Injuries—A Biomechanical Analysis of the Jewett Hyperextension Orthosis. Patwardhan AG, et al., *Spine* 15(7):654-661, 1990.

Role of Facet Orientation in Producing Thoracolumbar Spinal Fractures. Gilbertson L, Goel VK, Patwardhan AG, *Biomechanics Symposium*, AMD 120:357-360, 1991.

The Biomechanical Function of "Three-Point" Hyperextension Orthoses. Gilbertson L, et al., *Adv Biomed Eng Med Phys* (in press).

Three-Dimensional Instability Patterns of the Thoracolumbar Burst Fracture. Slosar PJ, et al., *Adv Biomed Eng Med Phys* (in press).

[342] A Modular Fiber Composite Orthotic System

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Sponsor: VA Rehabilitation Research and Development Unit (Core Funds)

Purpose—The objective of this project is to develop and evaluate a new modular fiber composite (MFC) lower extremity orthotic system consisting of components made of lightweight, high strength fiber composite materials. The purpose of this experiment was to compare the durability of the MFC design with commercially available aluminum and graphite designs.

Progress—Fatigue testing of the aluminum, graphite, and MFC uprights has been completed.

Methodology—In the fatigue tests, three types of knee-ankle-foot-orthosis (KAFO) uprights (with attached knee joints), aluminum, graphite, and the MFC design, were tested using a computer-controlled MTS hydraulic testing machine. Fatigue testing used orthotic uprights and rigid, reinforced knee joints cyclically loaded in "three point bending" in the sagittal plane. This reinforcement allowed testing of the upright and its connection to the knee joint instead of testing the knee joint. The maximum bending moment and bending stress occurred at the center of the specimen at the connection of the upright and knee joint. Before testing, the loads associated with use of the orthosis were estimated and the testing fixture designed to simulate that loading. The goal was to compare the relative fatigue strength of the cross-sections and knee-joint connections of the three different designs.

Results—Results were analyzed using the durability index (d) which is defined as the sum of the products

of the number of cycles and the maximum bending stress at a given load. Specimens were cycled at up to about 2.5 Hz. The exact frequency of cycling depended on the load. Loading began at 80 lbs for 400,000 cycles, and was increased stepwise until the specimen failed. The durabilities at failure were: $d(\text{aluminum}) = 4.7 \times 10(10)$, $d(\text{graphite}) = 4.6 \times 10(10)$, and $d(\text{MFC}) = 9.5 \times 10(10)$. The graphite upright failed at a rivet hole, whereas the aluminum and MFC uprights failed by fracture through the upright. The absence of rivet fasteners, the "race-track" cross section, and the use of carbon fiber composites adds to the structural integrity of the MFC design. The fatigue pilot study demonstrates that the MFC upright design is twice as durable as existing designs in bending.

Future Plans—The plan is to develop and evaluate the MFC orthotic system by fabricating prototype orthoses, and by performing structural testing to redesign components for optimal performance and safety in preparation for use on patients. Ultimate strength testing in bending is underway. Torsion, another major cause of failure, may also be tested in the future. The ultimate goal is to transfer this new technology to the handicapped community through the private sector service delivery in orthotics.

Implications—The implications of the results are: 1) The hollow oval racetrack cross section of the uprights significantly increases strength in bending and torsion when compared to rectangular cross

sections of the same area. This cross section places composite material in the areas of highest normal and shear stresses, where it is most needed. 2) Composite materials should be more durable than metal bracing resulting in increased cost effectiveness. 3) Modularity and the absence of fasteners or binding agents not only increases strength, but will allow quick and easy replacement of only the broken

component without replacing other components. This would significantly decrease the long-term costs of orthotics in patients with permanent disability, who frequently break single orthotic components. 4) Modularity of design allows for accommodation of anatomical changes, thus allowing the design to be especially cost effective for children who sometimes need rebracing as often as twice yearly.

[343] CEDO: A Controlled-Energy-Dissipation Orthosis for Tremor Reduction in Activities of Daily Living

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Sponsor: *Burke Rehabilitation Center; National Science Foundation*

Purpose—People disabled by large amplitude pathological intention tremor (e.g., people who have multiple sclerosis or have had closed head injuries) are often incapable of undertaking activities of daily living independently in spite of normal strength. As a means of selectively suppressing relatively rapid oscillatory movements and exposing voluntary activity, these investigators have developed a 3-degree-of-freedom wheelchair-mounted compliant orthosis which dissipates energy in a frequency-dependent way. It has approximately the geometry of a standard commercial mobile arm support ("ball bearing feeder"), but incorporates computer-controlled magnetic particle brakes at each joint. The "elbow" brake is mounted on the support fixture and coupled to the joint by a parallelogram linkage in order to make it unnecessary for the user to move its mass when using the device. The brakes are controlled to behave as velocity-dependent dampers whose damping constant is adjusted as a function of end-point position. Functional activities in a large part of the normal seated range of motion are permitted.

Progress—Initial experiments conducted with eight people with tremor disability, including both simulated functional activities and objective tracking tasks, showed significant tremor reduction and improved signal-to-noise ratio. Several technical

changes to the system also were made as an outcome of this work, including revised control software, more exhaustive characterization of the system, simplified interchangeable limb-couplings, improved cosmetics, more readily manufactured brake mounts, and capacity for simulation of velocity-squared damping in addition to linear viscous damping. Data from the most recent subject testing are presently being processed. Preliminary results indicate that a brake with greater torque is needed at the elbow and that ataxia can be reduced as effectively as more rhythmic intention tremors.

Future Plans—Experiments will continue, using the above protocol. In addition, tests of longer term effects will be conducted, since the system may be viewed as a resistive exercise machine. Further, an investigation will be conducted of the effect on user performance of the system's force-velocity non-colinearity. (The device geometry does not produce resistive force aligned with velocity at the user's arm for all end-point locations.)

Discussions are presently underway with an orthotics manufacturer with a view to licensing the design for marketing.

Patents

Whole-Arm Orthosis for Damping of Tremor. Patent applied for: June 25, 1990.

[344] Further Development of a Water-Resistant Covering for Ankle Foot Orthoses (AFOs) During Recreational Activities

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Sponsor: *Easter Seal Research Institute of Ontario*

Purpose—The purpose of this research is to develop a durable and cosmetically appealing cover that provides protection and support of the asensitive lower limbs and ankle foot orthoses (AFOs) during recreational activities in and around the water. Abrasions from concrete and sand can develop into pressure sores and can cause disuse of orthoses, restrict activities, result in an increase in deformity, and even necessitate surgical procedures.

Progress/Methodology—Two different prototype swim cover designs underwent various static and dynamic tests on 20 subjects. The covers were

assessed for durability, ease of application, cosmesis, functional ambulation, water and sand resistance. While the final analysis is not yet complete, preliminary results indicate that the swim cover concept was well accepted by the parents/caregivers and the children themselves. In addition, the covers offered support and protection during watersports, which are not offered by anything currently commercially available.

Future Plans—Plans are underway to make the final product commercially available to certified orthotists.

[345] Concerted Action Mobility Restoration for Paralyzed Persons (MORE Project)

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Sponsor: *Italian Ministry for University and Scientific Research, Italian National Research Council*

Purpose—The Concerted Action MORE (MObility REstoration for paralyzed persons) has been launched by the COMAC BME (Committee for Management of Concerted Actions in BioMedical Engineering) in the framework of the fourth Medical and Health Research Program of the Commission of the European Communities. This 4-year program started in 1988 and involves more than 50 institutes located throughout the countries of the European Communities. The Concerted Action is directed toward those who are paralyzed as a result of spinal injuries (i.e., paraplegics, quadriplegics), cerebral palsy, or neuromuscular diseases—people who represent a high percentage of the physically disabled. However, many other disabled persons could also benefit from the results of this action.

The objectives of MORE can be summarized as follows:

- Stimulate research of new technologies having meaningful and beneficial application for disabled

users, particularly in the areas of: 1) new electrode materials, implantable multichannel stimulators, control strategies and implantation techniques for walking restoration in paraplegics; and, 2) new materials, ergonomics and design, seating and support systems, and control systems for technical aids for independent mobility.

- Multicenter trials of existing devices and new technologies, and the exchange of evaluation results among the centers involved in order to improve their value and reliability.
- Coordination of methodologies and protocols for technical, functional, and clinical evaluation of mobility aids. Technical evaluation is concerned with the technical quality and performance (e.g., materials, durability, safety, reliability, etc.) of equipment; functional evaluation is concerned with the effectiveness of equipment in meeting the actual needs of its disabled user; clinical evaluation is concerned with the effects on the user's health and the compatibility with the body as it

applies to some devices implanted or directly interfaced with the body (e.g., FES equipment).

- Gathering of research and evaluation results and dissemination to industries and/or rehabilitation professionals. For such purposes, a close relationship has been established with: 1) the ongoing Handynet project—a section of the second program of Action in Favor of Disabled People (HELIOS) run by the Commission of the European Communities through the DGV, aimed at setting up a computerized information network concerned with the technical and social resources for rehabilitation and social integration; and, 2) the CALIES program (Computed-Aided Locomotion by Implanted Electrical Stimulation) launched in the framework of the EUREKA program.

Progress—Seven topical workshops were organized to exchange scientific knowledge, to discuss technical, functional, and clinical results, to organize operational pilots, and to work out recommendations and guidelines for further actions. The publication of three books collecting the most valuable scientific papers presented in the workshops provided the means for dissemination of data, methodologies, results, and recommendations throughout the world. Exchanges of personnel among all the involved countries were organized to promote transfer of technologies and methodologies, multicenter trials of devices, and provision to clinical teams of suitable background for implementing advanced technologies for mobility restoration.

Circulation of test results among the six wheelchair testing institutes based upon Handynet forms and ISO standards provided the means for setting up an infrastructure for European disclosure of evaluation information. The creation of a clinical network for walking restoration in high-level spinal-cord-injured patients promoted the use of the same methods for patient selection, training, devices adaptation, and patient assessment.

A common interdisciplinary approach has been adopted, integrating technology (sensor, new materials, optoelectronics, neuroprocessors), and advanced methodologies for data processing, modeling, and statistics with the most recent acquisition in the field of rehabilitation, medical treatment for walking restoration, and independent living of the disabled.

Results—The Concerted Action ends in 1991 and the major achievements in these 3 years of activity can be summarized as follows:

- Techniques and algorithms for investigation of human gait models and functional evaluation of walking recovery in paralyzed patients.
- Creation of a European network for multicenter clinical trials of the assistive devices for restoration of walking in patients with high-level spinal lesions, using the same methods and protocols for patient selection, training, device adaptation, and patient assessment.
- Research into electrodes (surface and implantable) and stimulation patterns for functional electrical stimulation (FES), supported also by experiments on animals.
- Development of models for control strategies in walking by FES and their preliminary validation on patients.
- As a direct effect of the Concerted Action, more than 200 paraplegic patients in Europe are benefiting from advanced mechanical orthoses, and almost 20 are testing hybrid systems with FES.
- Investigation into the ergonomics of wheelchairs and into its influence on design parameters, construction aspects, prescription criteria, and fitting process.
- Study of technical testing techniques and methodologies and investigation into their comparability in view of promoting implementation of international standards.
- Development and validation of methodologies for consumer testing of wheelchairs.
- Identification of obstacles and solutions for wheelchair testing information disclosure in Europe to ensure coherence with either the ISO standards or the European Handynet information system.
- Definition of a preliminary agreement among the six European Wheelchair Testing Institutes to circulate the test reports, according to common guidelines, defined in the frame of the Concerted Action (particularly important in view of the 1992 free market), and publication of the first pilot volume including test reports of wheelchairs tested in 1990 and 1991.
- Promotion of an infrastructure for ensuring that the expertise of the testing centers will be ex-

ploited in the frame of the CEN Standardization activities that will begin by the end of 1991.

Recent Publications Resulting from This Research

Wheelchair Testing in Europe: Recent Advancements and Trends. R. Ronchi, R. Andrich (Eds.). Milan: Edizioni Pro Juventute, 1990.

Functional Electrical Stimulation: The State of the Art and the Future. M. Ferrarin (Ed.). Milan: Edizioni Pro Juventute, 1991.

Restoration of Walking for Paraplegics: Recent Advancements and Trends. M. Ferrarin, A. Pedotti (Eds.). Milan: Edizioni Pro Juventute, 1991.

[346] Evaluation Protocol in Walking Restoration of Paraplegic Patients

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Sponsor: Italian Ministry for University and Scientific Research, Italian National Research Council

Purpose—This project seeks to develop and apply an evaluation protocol to analyze the performance of paraplegic patients walking with mechanical orthoses. The aim is to obtain a tool for optimizing the external walking devices to each patient, both from a dimensional point of view and in terms of improving the training and functional use of the orthoses.

Progress/Methodology—A group of patients have been selected for this study with a level of spinal cord lesion varying from T3 to T10. After an initial period of exercise to strengthen the muscles of upper limbs and trunk, each subject was supplied with the orthosis (ORLAU-HGO Parawalker) and trained for 4 weeks, 2 hours a day. Different evaluations during the training period and after 4 months of functional use have been established working with a team consisting of a physician, bioengineer, physiotherapist, and an orthotist. Clinical, ergonomic, biomechanical, energy consumption, and bone mineral content assessments will be made. To evaluate the improvements on patient autonomy and ability during the training period, a set of ergonomic tests has been established including the measure of the time to put on and take off the orthosis, to stand up and sit down, and to walk 30 meters in normal conditions together with the heart rate time course. A multifactorial gait analysis system has been adopted to collect simultaneously all significant data about walking assisted by orthoses. The system consists of an ELITE system for kinematic analysis, a force platform for ground reaction force detection, an 8-channel electromyograph to record

myoelectric activity of supraspinal muscles, and a personal computer with suitable software to store, process, and graphically represent all data collected.

Preliminary Results—This pilot project is still under development and the patients have just finished their training with Parawalker. We have collected data about patient performances evolution during the training period. Preliminary biomechanical data give the impression that much useful data can be collected in order to quantify the functionality of the walking system and obtain important indications on how to optimize the orthosis for the individual patient. The degree of rotation between pelvis and shoulders and the values of maximum lateral sway seem particularly interesting. Furthermore, the distribution of load between crutches and calipers, detectable by analyzing ground reaction forces, could give important information about the efficiency of walking strategy adopted by the patient.

Future Plans—We plan to complete the analysis of the collected data and compare them with the data that will be acquired after 4 months of functional use of the orthosis. In addition, similar assessments on another group of patients using other orthoses (LSU-RGO) are planned, in order to accomplish comparative evaluations.

Recent Publications Resulting from This Research

3-D Analysis and Modelling for Evaluation and Adaptation of Assisted Walking. Ferrarin M, Palmieri R, in Proceedings of the EEC-COMAC-BME Workshop on New Theoretical and Applied Approaches in the Restoration of Impaired Motor Control, T. Sinkjaer (Ed.), Aalborg, Denmark, 1991.

[347] Evaluation of a Powered Orthosis for People with Upper-Limb Weakness Due to Amyotrophic Lateral Sclerosis (ALS)

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Sponsor: National Health Research and Development Programme (Health and Welfare Canada)

Purpose—This project's objectives are to: 1) develop the components and techniques that are necessary for the provision of a powered orthotic device for the enhancement of upper-limb movement (PODEUM); 2) evaluate the benefits of providing PODEUM to individuals with ALS; and, 3) identify the population for whom PODEUM would be most beneficial. To this end, a pilot investigation is being conducted to evaluate a PODEUM. Five people with flail arms due to ALS have been fitted with PODEUM. PODEUM provides powered flexion/extension of the user's elbow joint combined with pronation/supination and powered prehension/release, and is controlled by procerus, frontalis, and temporalis myoelectric signals. PODEUM may also be applicable to quadriplegics.

Methodology—PODEUM consists of a total arm brace, two powered actuators, and a control system. The brace is comprised of two spring-loaded elbow hinges, two steel rods (a rigid rod corresponding to the ulna and a telescoping rod corresponding to the radius), and a handpiece with a single axis hinge that opens and closes the hand in a palmar grasp. The elbow hinges are flexed by a powered winch. The winch contains a motor/gearbox assembly that is coupled to a timing belt. By attaching the timing belt to the telescoping radial rod through a cable, a diagonal force is exerted on the rod, causing it to extend. The effect is to flex the elbow and partially supinate the forearm at the same time. This preprogrammed motion is intended to facilitate self-feeding by allowing the forearm to be prone at table level when the user grasps food, and supine when the food reaches the user's mouth. A powered linear actuator effects hand opening and closing.

Myoelectric signals from the frontalis, procerus,

and temporalis muscles on the subject's forehead are used to control the elbow and hand. These muscles were chosen because they are usually unaffected by ALS. Two active electrodes are positioned on the subject's forehead. The precise control strategy is customized for the individual. Typically, one type of facial movement is used to open the hand and extend the elbow and a second movement is used to flex the elbow and close the hand. A combination of movements is used to switch between hand and elbow control. For each subject five patterns of muscle activity are considered: 1) lowering the left eyebrow; 2) lowering the right eyebrow; 3) lowering both eyebrows; 4) raising both eyebrows; and, 5) biting down to activate temporalis bilaterally. Through a combination of gain adjustments and strategic positioning of the electrodes, a pattern of muscle movements is chosen to activate the electrodes individually (for flexion/extension), and together (for mode switching). The electrodes are secured to the forehead with a custom-molded headband.

In some cases, chewing of solid foods interferes with one of the electrode channels. To avoid this problem, this channel is connected so that it controls closing of the hand. In this way, the user can chew without dropping the food or utensil in his hand.

Progress—Eleven individuals with ALS have been referred for fitting with PODEUM. Of these, four declined to participate or were not accepted because they had functioning upper-limbs at the time of referral, two were not accepted due to respiratory or swallowing difficulties, and five were fitted with PODEUM. In addition, one device was provided to an independent rehabilitation center for external evaluation with a subject selected at that center.

[348] Further Development of a Protective Helmet for Disabled Persons

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Sponsor: *National Health Research and Development Programme (Health and Welfare Canada);
Canstar Sports Group (Cooper Canada Limited)*

Purpose—The objective of this project was to develop protective headwear which provides effective protection for persons who are susceptible to head and/or facial injuries. The specific goals are: 1) to develop a second-generation prototype that provides appropriate anatomical protection, is custom-fitted, comfortable to wear, looks attractive, and is reasonably priced; 2) to evaluate the biomechanical performance of the helmet; and, 3) to assess the subjective acceptance and performance of the helmet through clinical trials.

Methodology—The new helmet developed consists of three parts: an anterior section, a posterior section, and a chin protector. Each part is comprised of a hard polyethylene outer shell and a soft polyethylene foam liner. Both sections are industrially fabricated in two sizes to accommodate individuals from age 5 years old and up. The anterior aspect of the assembled helmet is configured to extend out to provide clearance for the face following a forward fall.

The performance of the helmet was measured through both biomechanical testing and clinical trials. Both quantitative and qualitative biomechanical tests were conducted to evaluate the protective nature of the helmet. At the biomechanical test laboratory at Cooper Canada Limited, the helmet was tested to evaluate its ability to meet the impact attenuating requirements of the Canadian Standard Association (CSA) for hockey helmets. For the cranial areas tested, the transmitted forces measured were below the threshold limits set in the CSA Standard.

To evaluate the effectiveness of the helmet in offering facial protection, an impact test rig was designed and constructed. Since no valid acceptance limits for evaluating this aspect of protection were available, the relative performance of the research

and custom-fabricated helmets were investigated. Imprints of headform excursion demonstrated that a properly fit production helmet appeared to provide facial protection at least equal to that provided by the custom-fabricated version.

Nine subjects having various neuromuscular and seizure disorders, and who were users of custom-fabricated helmets, participated in the clinical evaluation of the modular headwear. Clinical trial periods lasted 6 to 10 weeks. The subjects returned to the clinic for a followup visit, whereupon they were asked to judge specific features of the helmet and rate its performance. The project orthotists who performed the initial fittings inspected and evaluated the service condition of the devices. Clinical impressions of the post-trial fit were also solicited.

Results—The research helmet was found to be an orthotic device that could be readily dispensed in a clinical setting in one appointment. On the average, it required 2 hours to measure, evaluate, and fit the client. Comments from caregivers suggested that the helmet was well-received. They appreciated the speed with which the helmet was fit, the cosmetic aspects of the helmet, and foremost that it offered the protection needed during the trial period.

Preparation is underway to offer the helmets commercially through Variety Ability Systems Incorporated (VASI). It is envisaged that the helmets will be available in kit form to certified orthotists only after they have taken a training course that instructs them on the proper assembly and fitting procedure.

Recent Publications Resulting from This Research

Development of a Protective Helmet for Persons with Disabilities. Ryan SE, et al., in Proceedings of the 14th Annual RESNA Conference, Kansas City, MO, 361-363, 1991.

[349] Spherical Coordinate Virtual Environment for Limb-Loading Experiments

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Sponsor: *National Institute on Disability and Rehabilitation Research; Burke Rehabilitation Center*

Purpose—This manipulandum was built as an experimental facility for conducting experiments on human motor control, in particular, for research on disabling tremor. It is essentially a two-degree-of-freedom spherical coordinate robot controlled via digitally-supervised analog loops to behave as a virtual environment. In addition to combinations of inertia, damping, and elasticity, it can simulate detents, rigid walls, and other physical elements. It can also introduce force perturbations. It is based on two brush-type DC servomotors driven by pulse-width-modulated amplifiers. Direct coupling between the device handle and the motor shafts is accomplished by a unique gimbal linkage. For tremor research, the system permits limb loading as a system identification technique (i.e., as a means of modeling tremorogenic mechanisms from their response to changes in apparent limb impedance).

Progress/Methodology—The system has been subjected to extensive tests to fully characterize it. Early trials demonstrated the ability to alter a subject's tremor in frequency and amplitude by elastic loading.

Recent experiments with four subjects with intention tremor (two head-injured and two with

multiple sclerosis) at the Burke Rehabilitation Center utilized the manipulandum in isometric mode (i.e., with the motor shafts locked and the subject required to produce forces in order to track a video target). The direction of the required force in a given trial requires either just shoulder muscle activity or both shoulder and elbow. The idea in this extremely simplified protocol is to determine whether voluntary activity at one joint induces intention tremor at the other.

Future Plans—Data analysis has just begun. The goal is to draw conclusions about tremor mechanisms, and in particular, the presence or absence of neural cross-talk between limb degrees of freedom for tremor generation. Guided by the results from present experiments, the protocol will be generalized to include whole-limb movement and partial splinting to extend our conclusions.

Recent Publications Resulting from This Research

A High Performance Two Degree-of-Freedom Kinesthetic Interface. Adelstein DA, Rosen MJ, presented at the Engineering Foundation Conference on Human Machine Interfaces for Teleoperators and Virtual Environments, March 1990.

[350] MED Arm: A Six-Degree-of-Freedom Orthosis Simulator for Tremor Research

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Sponsor: *National Institute on Disability and Rehabilitation Research; Burke Rehabilitation Center*

Purpose—The focus of this project is the design, fabrication, and testing of a 6-degree-of-freedom (DOF) computer-controlled energy-dissipating manipulandum known as the MED (Modulated Energy Dissipation) Arm. Its function is to serve as a test bed for assessment of the effects of resistive loads on people disabled by movement disorders

during functional whole-arm movements. The device may be viewed as a human-interactive orthosis-emulator which will allow experimental evaluation of the effectiveness of practical designs for tremor-suppression orthotics with a single laboratory facility. It is also expected to serve as: 1) a tool for objective measurement of tremors; 2) a differential

diagnostic system; and, 3) a prototype compliant restraint system for tremor reduction in functional activities.

In its initial configuration, the MED Arm controls its magnetic particle brakes to behave as viscous dampers. Control of brake torque is open-loop, with the system's endpoint 6-axis force/torque sensor serving only for data acquisition. The "shoulder" and "elbow" joints of the Arm are linked mechanically, effectively providing one rotational joint and one prismatic joint. As a result of this, and the design of the three distal DOF, the forces and torques produced by the brakes all operate through a single end-point, and all act along and about, respectively, orthogonal axes. It is this property that gives the system its force-velocity colinearity.

Progress—Fabrication and bench-testing of the MED Arm have now been completed. A number of objective tests have been conducted to characterize the performance of the MED Arm. Results include the following: 1) the brakes used for the distal three axes produce a maximum force with which translations at the end effector can be resisted of 14 lbf; 2) the measured maximum translational friction at the end-effector is 0.25 lbf or less, depending on direction; 3) force-deflection characteristics at the Arm endpoint with the brakes at maximum current to prevent slip showed a worst-case stiffness of 19 lbf/in; and, 4) the Arm is completely counterbalanced so that no weight is perceived, only inertia. The effective passive inertia of the Arm at the endpoint is 10 lbm or less, depending on the direction of applied force.

Methodology—The initial experimental protocol included two components described as Abstract and Functional. All parts of both protocols were performed at four levels of damping chosen to span the range of values provided by the Arm. In the Abstract tests, subjects were asked to observe a randomly moving target on a video screen and track it by movements of the Arm in a vertical plane aligned with the screen. For the Functional testing, a protocol was developed based on a standard clinical rating system. Activities performed by the subjects "wearing" the Arm included nose-to-finger tests, handwriting, Archimedes Spiral, water pouring, soup eating, and name spelling on an expanded QWERTY keyboard.

Results—Preliminary human testing has been performed with three subjects, two tremor-disabled and one able-bodied, to begin evaluation of the effects of using the Arm. Data shows clear improvement with increased damping in the Functional test performance for both disabled subjects and a corresponding change in Abstract test results for one of them. One outcome of the initial experiments has been the installation of a new limb coupler which allows for different limb sizes and permits quick release.

Future Plans—Experiments of the types described above will continue with additional subjects. Additional development tasks will be undertaken, including revision of the control algorithms to produce more sophisticated loading schemes. The effects on tremor of long-term use as a functional aid will also be measured.

[351] Damped Wrist Orthosis for Distal Intention Tremor

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—People with tremor or ataxia resulting from head injury, multiple sclerosis, or other degenerative diseases lose functional independence due to the resulting inaccuracy of purposeful movements. Research by the tremor group in this laboratory has shown that the application of viscous damping

across tremorous joints can improve the signal-to-noise ratio of movements to a functionally significant degree. While several prototype functional assistance devices incorporating this principle have been designed and built here, all have required mounting to a frame of reference external to the

user (i.e., none have been wearable). The purpose of this project is to design and evaluate a wearable damping orthosis as a means of attenuating tremor in wrist extension/flexion for people disabled by distal tremor.

Progress—Several mechanical schemes have been devised and evaluated for incorporating viscous damping into a wrist orthosis while satisfying constraints related to weight, bulk, cosmesis, interference with functional activities, and heat dissipation. One concept emerged as clearly superior in terms of the amount of damping available from a package that is small and distributes its mechanism over the limb in order to avoid localized projections. The idea is based on coupling the extension and

flexion of the hand with respect to the forearm to the shearing of viscous grease between two flexible surfaces mounted on the back of the hand and arm. Present efforts are devoted to identification of damping and sealing materials and experimental determination of dimensions to obtain the desired mix of low stiffness and high damping.

Future Plans—When a prototype that meets specifications is completed, it will be subjected to bench testing to determine its temperature dependence and fatigue resistance, and the reliability of its seals. In addition, people with distal tremor will be identified and asked to use the new orthosis under controlled and daily living conditions to establish what design changes are needed to meet our goals.

[352] Rehabilitation of Advanced Tarsal Disintegration with the Use of a Fixed Ankle Brace

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Sponsor: *Poona District Leprosy Committee*

Purpose—In advanced cases of tarsal disintegration (TD), especially the septic variety (Gr. IV deformity), if the infection is not brought under control with rest and immobilization, it surely leads to the inevitable below-knee (BK) amputation.

In Europe and the United States, these cases may be better off with an early BK amputation and a well-fitting prosthesis. However, in India, because of certain traditions and practices, we try to preserve the limb length and avoid BK amputation as long as possible.

Almost all the daily activities of a rural Indian are carried out on the ground. This necessitates the patient sitting on the ground—either squatting on the ground, sitting cross-legged, or with legs and feet to one side. All these postures are difficult or impossible with a BK prosthesis.

Also, because of religious traditions, leather footwear is not allowed in some houses. When a person enters a house, he removes the prosthesis and moves about on his buttocks with the help of his upper limbs. Then there is the added danger of

carpal disintegration and getting ulcers on the already insensitive hands.

Methodology/Progress—We have studied 12 cases of advanced TD. Infection was controlled with antibiotics and rest, and though the bony lesion was advanced, we conserved it with prolonged immobilization with plaster. After 3 to 4 months, when there were signs of stability of the lesion, they were prescribed a fixed ankle brace (FAB) or a patellar tendon-bearing FAB (PTB/FAB) with rocker, and graded weight-bearing was started. FAB with rocker abolishes the heel-toe pattern of walking and the tarsus is protected from undue stress and strain during ambulation.

Results—In all these cases, we were able to make the patient walk on the diseased limb with a FAB for a period of at least 2 years, we conserved the advanced TD cases, avoided a BK amputation, and preserved the limb length.

[353] New Variety of Fixed Ankle Brace

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Purpose—Tarsal disintegration (TD) is a known complication of leprosy patients. Treatment consists of control of infection if any, and prolonged plaster immobilization. After the lesion is under control, patients are made ambulatory with the help of a fixed ankle brace (FAB), made of metal and leather.

One of the disadvantages of the FAB where a metal frame is used is that it is heavy and cumbersome. If the FAB is not fastened properly during walking, there may be friction between the molded sole of the foot and even telescoping of the leg against the metal uprights. This causes ulceration of the skin in the insensitive feet of leprosy patients. If there is misalignment of the metal footplate and rocker, it may subject the foot to undue stress and strain.

Progress/Methodology—We have developed a new FAB which is made from a plaster cast of the entire diseased foot and lower leg. The inner fabric is of stockinette impregnated with araldite. Two metal strips reinforce the medial and lateral aspects of the FAB, especially across the ankle joint, where there is maximum stress.

The mold of the entire posterior part of the lower half of leg and ankle continues distally as a molded footpiece. A molded plastazote insole rests on this resilient footpiece which is fitted with a rocker. The edges of the footpiece are molded on all sides to protect the insensitive toes from accidental injury. The FAB is fastened in place with 3 to 4 velcro leather straps. These are anchored to the medial and lateral vertical reinforcing metal strips. These can be made in one-fourth the time it takes to make a conventional metal FAB.

Preliminary Results/Implications—Thirty-nine leprosy patients with tarsal disintegration have been fitted with this FAB. It is approximately half the weight of the conventional FAB, thereby reducing friction and ulceration; it is better accepted cosmetically, very little maintenance is required; patients find ambulation easier, and even claim faster ulcer healing after its use. This is still to be proven in planned studies, but may be so because of better acceptability, and hence regular use.

[354] Modular Wrist, Hand, and Finger Orthoses

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Sponsor: Scottish Home and Health Department

Purpose—A wide variety of clinical conditions require the supply of upper limb orthoses. Experience in Dundee has shown that it is possible to considerably reduce the time required to fabricate and fit these devices by making use of standard modular components. This project is designed to exploit this experience by developing a modular system of components capable of being quickly assembled to form a wide range of orthotic configurations.

Following design of the system, a clinical evaluation of the prototype components will be conducted and commercial arrangements sought for the future manufacture of the system.

Methodology—Development. The prototype system comprises two sets of components referred to as the interface components and the connecting components.

The complete set of interface components manufactured from thermoplastic comprises: two forearm units (not handed); three hand units (handed); three transverse finger bars (not handed); and, four differing-sized finger loops.

The interconnecting units are defined as with dynamic or static characteristics.

The complete set of dynamic interconnecting units which are manufactured from coiled spring wire consists of: two sets of components for the wrist hand connection (medial and lateral differing); three sets of components for the hand transverse bar connection (medial and lateral the same); and, three sets of components for the transverse bar finger connections.

At present, one single-static connecting unit is intended for use for all connections between interface components.

Clinical Evaluation. A multicenter clinical trial will be conducted to verify the ability of the system to meet the clinical and functional requirements, to confirm the ease of assembly and application, to

confirm adequacy of fit, and to assess the mechanical reliability of the system.

Progress—Development of the complete set of interface components has been completed. The designs and tooling for these components have been transferred to Hugh Streeper & Son, Ltd., who will in future manufacture the system and market it as the "Tayside" range of orthoses. Further development of the static connecting components continues.

Documentation comprising a "User Manual" and an "Evaluation Form" have been produced, and it is anticipated that the clinical trial will be completed early in 1992.

Future Plans—Results of the clinical evaluation with recommendations regarding changes in the design will be forwarded to the manufacturers. Once the development of the static connecting unit is complete, it will be offered to the manufacturer to broaden the scope of application of the system.

XIII. Psychological and Psychosocial Disorders

[355] Rehabilitation Effects of Expectation, Reward, and Activity on Subtypes of Schizophrenia

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Sponsor: VA Rehabilitation Research and Development Service (Project #D515-RA)

Purpose—This research investigates the benefits of productive activity in the rehabilitation of patients with a diagnosis of schizophrenia. Key questions are: 1) Does greater expectation for productive activity lead to more productivity? 2) Does greater productivity lead to better rehabilitation outcome? 3) Does payment act as a reward for schizophrenic patients in a work program leading to greater productivity, greater job satisfaction, and increased self-esteem? 4) Does greater expectation increase the likelihood of relapse and rehospitalization? and, 5) Are subtypes of schizophrenia based on psychological and neurobehavioral measures useful predictors of rehabilitation outcome?

Methodology—One hundred and fifty patients with DSM-III-R diagnoses of schizophrenia confirmed by SCID are being recruited from the general psychiatric service, stratified by prior work function and negative symptoms, and randomly assigned to one of three levels of expectation for work: 20 hours ("High Expectation," N=60), 10 hours ("Low Expectation," N=60), or no hours ("Self-regulation" control condition, N=30) of work required per week. All subjects are offered work through the Incentive Work Therapy (IWT) program. The IWT provides up to 20 hours of work per week in placements throughout the medical center with duties similar to those of regular hospital employees. All subjects attend weekly group sessions where, across all conditions of expectation, support is provided, level of expectation is reinforced, and weekly information on productivity and measures of clinical status (BPRS and PANSS) are obtained. Research staff evaluate productivity through on-site monitoring (Work Personality Profile), and supervi-

sors complete biweekly evaluations of performance (Minnesota Satisfactoriness Scale). Half the subjects receive weekly pay at \$3.40/hr for 6 months, and half are offered work without remuneration. Subjects are evaluated at baseline on demographic, neurobehavioral (negative symptoms, Wisconsin Card Sort, Continuous Performance Task, Thought Disorder), and productivity variables, and reevaluated at 6 and 12 months to assess clinical status, productivity, and other measures of rehabilitation outcome.

Progress/Preliminary Results—Rater intra-class R's for the PANSS (positive=0.76, negative=0.86, general=0.76), the BPRS (positive=0.79, negative=0.75, general=0.79), the WPP (mean=0.81), and the Gorhams Proverbs Thought Disorder Index (mean=0.91) have been determined. Ninety-seven subjects have entered the study and been randomized in the first year and 10 months. Seventy-four subjects have completed the 6-month intervention and follow-up evaluation, 36 have completed the 12-month follow-up intervention. Of 42 patients assigned to work without pay, 26 (63%) declined to continue in the active intervention; of 46 patients randomized to pay conditions, seven (15%) have discontinued participation in the first month, suggesting pay is a robust predictor of work participation.

While analysis of main effects would be premature, some findings examining symptomatology, work performance and other measures have emerged. Symptomatology has predicted behavior at work along a number of dimensions including work skills, and social skills. Randomization into the paid condition has predicted higher levels of productivity

in the following 6 months, and improvements in quality of life and depressive symptomatology. Lastly, the PANSS has been found to be nonequivalent to, and have superior predictive power over, the BPRS.

Implications—These preliminary results suggest symptomatology plays a role in work performance and is important to assess when schizophrenic patients are referred for vocational rehabilitation. Findings also suggest that payment is a crucial variable which should be considered in the guidelines for programs appropriate to the rehabilitation of schizophrenic veterans. We have produced manuals of group procedures for inducing various levels

of expectation and are trying to produce more refined tools for the assessment of vocational functioning. These technologies may be easily transferred to other settings and used as clinical tools in rehabilitation of veterans with schizophrenia.

Recent Publications Resulting from This Research

Comparison of the Positive and Negative Syndrome Scale with the Brief Psychiatric Rating Scale. Bell MD, et al. Paper presented at the 144th Annual Meeting of the American Psychiatric Association, New Orleans, LA, 1991.

Symptoms and Work Performance in Patients with Schizophrenia. Milstein RM, et al. Paper presented at the 144th annual meeting of the American Psychiatric Association, New Orleans, LA, 1991.

Object Relations Deficits in Subtypes of Schizophrenia. Bell MD, Lysaker PH, Milstein RM, *J Clin Psychol* (in press).

[356] Post-Traumatic Stress Disorder in Spinal Cord Injury Patients

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Sponsor: *American Association of Spinal Cord Injury Psychologists and Social Workers; Seattle VA Medical Center*

Purpose—Symptoms of post-traumatic stress disorder (PTSD) are often chronic and disabling, and occur at an alarmingly high incidence in diverse populations of individuals exposed to extreme traumatic stress. The severity of the trauma and extent of resulting disability associated with spinal cord injury (SCI) places patients at risk to develop PTSD symptomatology in a manner characteristic of other traumatized populations. The primary objective of this study is to assess the prevalence and longitudinal course of PTSD symptomatology in a population of veteran males with traumatically induced SCI. A secondary goal is to examine individual differences that predict the development and course of PTSD in SCI patients.

Methodology—Variables to be included in the analysis as potential risk factors include: 1) the presence and perceived supportiveness of significant others in the patient's social/family environment; 2) the manifestation of an acute generalized stress reaction shortly after the traumatic injury; and, 3) the extent to which the patient's accident resulted from an act of imprudence or poor judgment versus an event beyond his control. Research with other traumatized populations demonstrates the utility of these vari-

ables in accurately discriminating individuals with and without PTSD symptoms. Subjects will be 60 male veteran patients treated on the SCI Unit at the Seattle VA Medical Center. All subjects will be selected on the basis of having been admitted to the inpatient SCI Unit with an acute SCI resulting from a traumatically induced accident. A multimethod strategy employing interview and psychometric measures will be used to diagnose PTSD symptoms and assess predictor variables. The following measures will be administered: 1) the Structured Clinical Interview for DSM-III-R; 2) the Mississippi Scale for PTSD, SCI Version; 3) the Impact of Events Scale; 4) the Symptom Checklist-90-R; 5) the Purdue Social Support Scale; and, 6) clinician nurses' ratings of the degree to which imprudent behavior and poor judgment contributed to a patient's accident.

Patients will be administered the assessment battery at 2 weeks following admission to the SCI Unit, 2 months following admission, and 1 year post-discharge. The question of the prevalence of PTSD symptoms will be answered by calculating descriptive statistics from scores provided by the structured interview and psychometric indices measuring PTSD. Nonparametric statistics (Chi square)

and repeated measure analyses of variance will be used to analyze the temporal course of PTSD symptoms across the three assessment periods. Finally, multivariate correlational analyses (multiple regression and discriminant function analysis) will assess the relative contribution of selected predictor variables to various measures of PTSD symptom status. The study of PTSD in SCI populations has been ignored in the literature, despite convincing evidence that these patients are at risk for developing the disorder.

Future Plans/Implications—Study of the epidemiology of PTSD symptoms in this population will enable us to discover if this disorder occurs at problematic levels as hypothesized. The longitudinal course of PTSD will be investigated to determine whether this disorder represents a transient adjustment reaction that resolves spontaneously, or is a chronic pattern of maladjustment requiring more extensive treatment. Finally, investigation of risk factors associated with development of PTSD symptoms may facilitate prompt identification of vulnerable patients and early intervention efforts.

[357] Longitudinal Changes in Adjustment After Spinal Cord Injury: I

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Purpose—The purpose of this research is to study the psychosocial, vocational, and medical adjustment of persons with spinal cord injuries (SCI) over extensive periods of time after injury. The most important aspects of this study are the prediction of survival from psychosocial adjustment variables and the relationship of employment to biographic and adjustment status.

Progress—Data have been collected over a 15-year period from 1974 to 1989, with three stages of data collection completed thus far.

Methodology—A longitudinal design has been used to study life adjustment after SCI. Two study samples have been used to date, covering three stages of data collection. Sample 1 began participating in 1974 (stage 1) and Sample 2 was added in 1985 (stage 2). A third sample was identified for a fourth study stage, to be implemented in 1993. All participants were identified from case files of former recipients of urologic services at a Midwestern university hospital clinic prior to 1985. There were three screening criteria for inclusion: 1) a traumatic spinal cord injury; 2) the injury was at least of 2-years duration; and, 3) subject at least 18 years old at time of study.

The Life Situation Questionnaire (LSQ) and the Multi-Dimensional Personality Questionnaire

(MPQ) were the instruments used. In stage 1 (1974), the LSQ was mailed to all individuals in Sample 1. In stage 2 (1985), a revised LSQ was mailed to all Stage 1 respondents and to the newly added Sample 2. In the third stage (1989), both the LSQ and MPQ were mailed to all stage 2 respondents.

Of a potential 301 respondents in Sample 1, 256 (85%) returned usable materials in 1974. In 1985, 347 participants returned usable questionnaires: 154 of a possible 256 cases from Sample 1 and 193 from a possible 266 from Sample 2. The moderately high attrition is misleading (66% response rate), because a large number of participants were either deceased (N=46), could not be located (N=31), or were eliminated due to missing data (N=15). In the third study stage, 286 of the 347 respondents from 1985 again completed usable materials (82% response rate).

The LSQ was developed in 1974 to measure mostly objective information on a broad range of areas relevant to persons with SCI and was revised in both 1985 and 1989. The MPQ measures three higher-order dimensions, 11 primary personality dimensions, and six validity indicators and was developed for use with nonpsychiatric populations.

Results—Several significant findings were identified: 1) psychological, social, and vocational adjustment was correlated with length of survival; 2) employ-

ment history was related to adjustment and to biographic status; 3) life satisfaction was predicted by other variables; and, 4) adjustment remained stable over a 15-year period.

Implications—This research has been instrumental in validating the need for a comprehensive rehabilitation program by identifying relationships between nonmedical and medical outcomes (including survival), and between employment and adjustment.

Future Plans—An application for funding has been made to consolidate the results of this 15-year study into a monograph for rehabilitation professionals. A fourth stage of data collection is planned. Both the LSQ and MPQ will again be mailed to all stage 3 respondents, as well as to a new study sample.

Recent Publications Resulting from This Research

- Prediction of Long-Term Survival of Persons with Spinal Cord Injury: An 11-Year Prospective Study. Krause JS, Crewe NM. In: Empirical Approaches to the Psychosocial Aspects of Disability, M.G. Eisenberg, R.L. Gluckauff (Eds.). New York: Springer-Verlag, Inc., 76-84, 1991.
- Adjustment to Life After Spinal Cord Injury: A Comparison Among Three Participant Groups Based on Employment Status. Krause JS, Rehabil Counsel Bull (in press).
- Employment After Spinal Cord Injury. Krause JS, Arch Phys Med Rehabil (in press).
- Life Satisfaction After Spinal Cord Injury: A Descriptive Study. Krause JS, Rehabil Psychol (in press).
- Longitudinal Changes in Adjustment After Spinal Cord Injury: A Fifteen-Year Study. Krause JS, Arch Phys Med Rehabil (in press).
- Marital Status and Adjustment to Spinal Cord Injury. Crewe NM, Krause JS, J Am Paraplegia Soc (in press).
- Mortality After Spinal Cord Injury: A Four-Year Prospective Study. Krause JS, Saari JM, Arch Phys Med Rehabil (in press).
- Prediction of Life Satisfaction After Spinal Cord Injury: A Four-Year Longitudinal Approach. Krause JS, Dawis RV, Rehabil Psychol (in press).

[358] Longitudinal Changes in Adjustment After Spinal Cord Injury: II

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Sponsor: *Shepherd Spinal Center*

Purpose—The purpose of this study is to investigate the psychological, social, and vocational adjustment among a large sample of individuals with spinal cord injury (SCI), stratified according to gender, race, and age at injury onset. It will provide data that will help to understand the adjustment of SCI-related minority groups. A secondary purpose is to use this database prospectively to identify predictors of important future health-related problems such as mortality, decubitus ulcers, and self-reported health problems.

Progress—All data collection for the current study stage has been completed. Presentations are being prepared for upcoming conferences and publications are being outlined. All data have been entered into a data file and preliminary analyses have begun.

Methodology—All participants were identified from case files of former Shepherd Spinal Center patients. The three screening criteria for inclusion were: 1) a traumatic spinal cord injury; 2) the injury was of at

least two-years' duration; and, 3) subject at least 18 years old at time of study. Three stratification criteria were used (gender, race, and age at injury).

A total 363 of a possible 572 individuals responded to the study. Of these, 203 were male (101 white males; 102 black males) and 160 were female (133 white females; 27 black females).

The Krause-Anson Quality of Life Index (KAQOLI), a revised version of the old Life Situation Questionnaire (LSQ), was developed in 1974 to measure mostly objective information on a broad range of areas relevant to persons with SCI. The KAQOLI maintained many similarities with the LSQ, particularly on psychologically relevant items. The current instrument improves on the LSQ both in item format, and because the current study will provide data on a less select population.

Results—No data analyses have been completed to date. Analyses will fall into two general categories: 1) data reduction/scale development; and, 2) comparisons among the cohorts. Scales are being devel-

oped via factor analysis of the larger item sets. The resulting scale scores will be compared as a function of gender, race, and age at injury onset.

Future Plans—In early 1993, the KAQOLI will again be sent out to the study participants. Secondary complications will be assessed and predictors of these complications will be identified using the current database.

Implications—This study will provide researchers and practitioners with a standardized measure of adjustment after SCI; identify differences in the impact of subgroups of individuals with SCI based on gender, race, and age at injury onset; and, will provide a broad base of data for future prospective studies.

[359] Change in Vocational Interests and Their Relationship to Adjustment After Spinal Cord Injury

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—The dual purpose of this longitudinal study has been to study the stability of interests over an 11-year period after spinal cord injury (SCI), and to examine the relationship of interest type and interest stability with quality of life, personality, and socioeconomic status.

Progress—The preliminary data on interests were collected between 1978 and 1980. The second stage of data collection was completed over the past year. All instruments have recently been scored and entered into a data file in preparation for data analysis.

Methodology—Two study samples were used. The first consisted of 117 spinal cord injured men who completed the Strong Interest Inventory (SII) in 1980. The second sample (N=41) participated in a national collaborative study between 1978 and 1980. All participants were sent the Strong Interest Inventory, the NEO personality inventory (NEO-PI), a measure of socioeconomic status (SES), and a revised version of the Life Situation Questionnaire (LSQ). Of the 158 potential participants, 107 responded, 14 were deceased, 12 could not be contacted, and 25 refused to complete the materials.

Results—Data from the earlier studies suggested that many of the activities and occupations which a large portion of individuals with SCI find interesting

and rewarding may no longer be physically possible following SCI, and that these interests are unlikely to change after SCI.

Data have yet to be analyzed in the current study phase. Analyses will include: 1) stability coefficients for all SII scales; 2) comparisons of SII scale elevations across the two times of measurement; 3) correlation of SII General Occupational Themes with LSQ adjustment scales; and, 4) stability of interests as a function of NEO-PI profile configuration and SES.

Implications—This study will generate data on the basic question of how much personality and interests change after a severe traumatic physical disability. This in turn will help rehabilitation professionals in predicting the types of program activities that are most appropriate for each individual.

Future Plans—All participant information (e.g., addresses, phone numbers) are being maintained on file in order to perform a future follow-up. This follow-up will likely take place in another decade and may include the use of a new participant sample.

Awards

Dr. Rohe was awarded the Outstanding Research in Service to the Handicapped for the first phase of this study.

[360] Psychological Factors Related to Restoration and Maintenance of Function After SCI

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Sponsor: National Institute on Disability and Rehabilitation Research

Purpose—Spinal cord injured patients differ in the rate of development and level of maintenance of activities of daily living (ADL) skills during and after rehabilitation. Although some of this variability is due to differing rates of neural recovery, psychological factors also have been implicated. It is important, therefore, that the relations among these factors be identified to improve rehabilitation outcome. The purpose of this study is to: 1) investigate the impact of psychological factors on the recovery and maintenance of neural function indexed by muscle strength; 2) assess the relative importance of psychological factors versus muscle strength on the development and maintenance of ADL skills; 3) illuminate the nature of coping styles and strategies employed by SCI patients; and, 4) identify effective and ineffective coping styles and strategies, and to explore possible distinction between strategies which are psychologically and functionally effective.

Methodology—Subjects will be included in this study if they have traumatic spinal cord lesion, are at least 18 years old, have at least a tenth grade education, and either did not sustain a concurrent head injury, or have sufficiently recovered from a concurrent head injury to permit valid completion of the various instruments. Initial evaluation will be conducted when the patient has been transferred to the rehabilitation unit. At that time, measures will be taken of coping styles and strategies (Ways of Coping Checklist), current mood (Multiple Affective Adjective Checklist), depression (Beck Depression Inventory), and attribution of blame (Six-Point Rating). Activity level and physical and occupational therapy will be assessed weekly during rehabilitation. The initial set of measures will be readministered the week preceding hospital discharge, and at 6, 12, and 24 months following discharge. In addition, muscle strength evaluation and a functional assessment scale (Quadriplegia Index of Function) will also be administered. These data will permit us to identify: 1) what coping

strategies are employed by individuals with recently acquired spinal cord injuries; 2) which coping strategies are associated with greater manifest effort in rehabilitation therapy; 3) to what extent the psychologic factors produced disparities between functional potential and achievement in both acute and chronic phases of SCI; and, 4) the relationship between psychologic factors and recovery and maintenance of muscle strength.

Preliminary Results—Data analyzed thus far indicate patients may be dichotomously grouped into those who display consistently "high" effort, and those whose effort is "variable" over the course of rehabilitation. Patients who displayed consistently high effort were no more likely to achieve gains in muscle strength (assessed with MMT at 2 and 4 months post-injury) than were those who were variable in effort. Further successful achievement of independence in self-care skills is strongly related to muscle strength (measuring both muscle strength of biceps and ECRs) and functional skills (Quadriplegia Index of Function) at 3, 6, and 12 months post-SCI. Variable effort patients were somewhat more likely than high effort patients to achieve independence in self-care skills. This may be attributable to strong autonomy needs resulting in a less compliant patient, but a more independent individual. A third hypothesis investigated was the relationship between depression (as measured by the Beck Depression Inventory), and recovery of muscle strength. Depression in our SCI patients during rehabilitation is fairly low; there is no relationship between neurological recovery and level of depression. Furthermore, a careful analysis of patient responses to the depression inventory reveals that most items endorsed are vegetative-somatic in nature. These symptoms may be reflective of the sequelae of SCI, rather than clinical depression.

Future Plans/Implications—The importance of this study lies in its potential to identify and clarify the

role psychological factors play in neural and functional recovery.

Recent Publications Resulting from This Research

Depression After Spinal Cord Injury: Relevant vs. Irrelevant

Indicators. Reidy K, Caplan B, Arch Phys Med Rehabil 70:826, 1990.

Refusing Treatment During Rehabilitation: A Model for Conflict Resolution. Reidy K, Crozier KS, Western J Med 154:622-23, 1991.

[361] Assessment and Prevention of Chemical Dependence Following Spinal Cord Injury

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Sponsor: National Institute on Disability and Rehabilitation Research

Purpose—Chemical dependence can be related to the cause of spinal cord injury (SCI), can impair learning during rehabilitation, and can limit the vocational, social, and psychological adaptation made by individuals following SCI. This 5-year, prospective project will build upon an earlier study of the prevalence of drug and alcohol use and abuse by persons with SCI by examining: 1) the natural history of substance use following SCI; 2) the efficacy of rehabilitation staff in identifying and referring individuals with histories of chemical abuse; 3) the relationship between rehabilitation outcome and substance use by persons with SCI; and, 4) the success of referral to and treatment of substance use problems in preventing future substance abuse.

Methodology—The earlier study focused on the effect of pre-injury drinking and drinking expectancies on coping after SCI. A preliminary analysis of project data examined the relationship between alcohol use, drinking expectations, and coping skills during first inpatient rehabilitation following SCI. A total of 69 persons completed Folkman and Lazarus' Ways of Coping Checklist and Christiansen, Goldman, and Brown's Alcohol Expectancy Questionnaire; they also reported intoxication at injury onset and frequency and quantity of drinking during the 6 months before injury. The median use was four drinks one to two times per week for the 84% who reported drinking. Intoxication at SCI onset was reported by 42%. Greater levels of pre-injury drinking were associated with expecting alcohol to enhance cognition, motor per-

formance, and relaxation, but not sexual performance, assertiveness, mood, arousal, or sleep. As expected, persons reporting intoxication at SCI onset also reported more pre-injury drinking than did persons not reporting intoxication. In addition, they reported a greater reliance on wishful thinking, detachment, self-blame, and isolation, and greater expectancies that alcohol would enhance relaxation, mood, and sleep than did persons who did not report intoxication at SCI onset. These results suggest that heavier pre-injury drinkers consume alcohol for specific reasons that may impede successful rehabilitation outcomes.

Rehabilitation staff may help patients by inquiring about the coping strategies and alcohol expectancies accompanying heavy pre-injury drinking to help patients understand the effects they desire from drinking and to seek alternative ways of satisfying these needs.

Progress/Implications—We undertook two national surveys during this project period to assess the knowledge of rehabilitation medicine professionals and residents in physical medicine and rehabilitation regarding assessment of and referral for substance abuse. Members of the American Congress of Rehabilitation Medicine (ACRM) were contacted by direct mail with personally addressed letters asking them to participate in a survey. ACRM members were surveyed regarding their knowledge of substance abuse, attitudes regarding patients' substance use, and referral practices for patients with substance abuse problems. A 47-item survey was completed by 1,211 professionals (37% response rate)

after two follow-up attempts. Respondents suspected that 29% of their patients with traumatic injuries had substance problems. Routine screening for alcohol and drug problems at their facility was reported by 30%. Substance abuse education for staff was reported by 50%; patient education regarding substance abuse was reported by 59%.

While 79% reported that their facilities had referral procedures for patients with substance abuse problems, only 44% reported making referrals. Patients were referred most often to Alcoholics Anonymous.

The results suggest the need for education regarding substance abuse assessment and treatment, facility policies, and referral procedures.

[362] Psychosocial Aspects of Functional Electrical Stimulation

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Sponsor: National Institute on Disability Rehabilitation Research

Purpose—Rehabilitation for persons who are paraplegic due to traumatic spinal cord injury typically emphasizes development of residual skills and adjustment to diminished body functioning. The development of technology to achieve stance and ambulation with functional electrical stimulation (FES) may significantly alter rehabilitation objectives and practice. This project seeks to develop a versatile, reliable, and safe system that allows stance in community settings. Such a valuable system can be expected to have a significant impact on the life of the user. The psychological status of both potential users and those unable to acquire this system is likely to be influenced as well. The psychological and social effects on individuals participating in a program in which personal benefits cannot be guaranteed may be critical to research success; however, possible effects have not been investigated. Careful selection of participants appears warranted based on a thorough review of previous coping skills and an ability to tolerate uncertainty. Identification of personal and situational characteristics associated with FES utilization and amelioration of FES technology problems could minimize waste of financial resources and personal investment and provide a basis for FES prescription in the future.

Progress/Methodology—The focus this year was on clarifying the apparent discrepancies between data obtained by nomothetic and idiographic methods. Nomothetic data come from questionnaires and self-report instruments designed to describe charac-

teristics of groups; this is the predominant method of contemporary psychology. Idiographic data are collected by interview and other methods that emphasize the uniqueness of individuals. Because the focus of study is different across these methods (individual differences defined by group characteristics, versus more relevant, but individually defined characteristics), the opportunity is provided to highlight different but complementary views. Additionally, some rehabilitation research topics are not suited to nomothetic approaches because the number of cases is too small or because the life context of interventions is what determines their effectiveness and appropriateness.

Resolving the apparent discrepancies that emerge in the two types of data was the focus of four intentionally selected FES cases. On the basis of nomothetic data, two cases were selected that appeared to be appropriate for FES research participation and two other cases appeared to be inappropriate; the conclusions drawn from idiographic data for these cases appeared to be either congruent or incongruent with the nomothetic cases. Thus, there was one case that appeared to be appropriate for FES participation on the basis of both nomothetic and idiographic data, one that appeared to be inappropriate considering both types of data, one in which idiographic data suggested the case was appropriate but where the nomothetic data were incongruent with this conclusion, and one in which nomothetic data suggested the case was appropriate but where the idiographic data were incongruent with this conclusion.

[363] Patient Perception of Blood Glucose Levels

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Sponsor: National Institute of Diabetes and Digestive and Kidney Diseases, National Institutes of Health; University of Virginia

Purpose—This study has been assessing the ability of some persons with Type I diabetes to perceive their own blood glucose (BG) levels, testing strategies for improving this ability in others, and measuring the blood glucose response to psychological and hormonal stressors.

Methodology—Over a period of 5 years, 80 subjects will be assessed in terms of ability to identify BG-relevant cues and BG level, therapeutic adherence, and various diabetic-relevant psychological variables. They will be hospitalized to assess BG response to psychological and hormonal stressors, and ability to counterregulate during insulin infusion. Three treatment groups will be formed to evaluate: 1) two different techniques to improve the subject's ability to perceive BG level and the impact of this improvement; 2) relationships of stress and

BG level and differences in vulnerability to stress; and, 3) the effects of steady insulin infusion via an insulin pump on BG reactivity to stress.

Preliminary Results—Previous studies have demonstrated considerable variability in an individual's ability to perceive his or her BG level and, to some extent, counterregulate it. It has also been observed that the metabolic status of some individuals is quite sensitive to psychological stress.

Future Plans/Implications—The ability to differentiate groups of diabetic individuals on the basis of metabolic reactivity to stress promises to be of use in patient management. If techniques can be found to improve patient perception of BG levels it may help patients improve their self-care decisions.

[364] Physiological and Psychological Mechanisms for Irritable Bowel Syndrome

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Sponsor: National Institute of Diabetes and Digestive and Kidney Diseases, National Institutes of Health; Johns Hopkins University

Purpose—This study seeks to further differentiate persons who have irritable bowel syndrome (IBS) into two groups (as previously hypothesized) on the basis of physiological data and behavioral investigations—those whose problem is fundamentally physiological and those whose problem appears to be fundamentally psychological. The study will also compare the psychological profile of persons with IBS who have consulted a doctor with those who have not.

Methodology—Physiological measures of bowel activity will be made: the incidence of colon slow waves greater than or equal to 15 seconds in duration, contractile activity in the colon over 24 hours, and the number of peristaltic contractions in

24 hours. These will be combined with psychometric inventories, an assessment of the relationship of stressful life events to exacerbation of bowel symptoms, and a questionnaire about medical clinic visits and medical disability days over 1 year.

Preliminary Results—It appears that persons with IBS should be categorized into two groups, differing by the physiological or psychological basis of the problem. It also appears that the occurrence of diarrhea or constipation is not indicative of a person's likelihood of belonging to one group or the other.

Future Plans/Implications—Differentiation of these two groups of IBS patients has important implications for the differing treatments that may prove to

be appropriate for each. Refinement of the measures under study may provide a more widely usable diagnostic tool, or may point the way toward

development of effective diagnoses. After differential diagnosis is achievable, the possibility of effective treatment will be increased.

[365] Patterns of Eating in Lean and Obese Humans

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Sponsor: *National Institute of Diabetes and Digestive and Kidney Diseases, National Institutes of Health; University of Pennsylvania*

Purpose—The long-term objective of this proposal is to apply to the treatment of obesity information gained from laboratory studies of the variables that control food intake.

Methodology—We will study the microstructure of eating behavior (chewing, palatability), electromyographic (EMG) recording of chewing, and ambulatory monitoring of chewing. The investigators will also test whether behavioral changes that are advocated by treatment programs for obesity, such as slowing the rate of ingestion, actually help people to eat less, and will differentiate between the eating behavior of lean and obese people.

Preliminary Results—1) EMG studies show that when food is relatively easy to chew, increasing the bite size increases the rate of intake at the beginning of the meal but does not necessarily increase the total amount eaten; 2) two laboratory studies on eating patterns of nondieting lean and obese subjects

showed that obese subjects select flavors to maximize palatability throughout a meal more than normal-weight subjects do; 3) a study showed that a gastric balloon has limited usefulness in the treatment of obesity; and, 4) slowing the rate of intake was *not* necessary to lose weight.

Future Plans/Implications—Groundwork necessary to develop an ambulatory system to monitor chewing has been done. Development of ambulatory monitor itself continues.

Investigators will determine whether behavioral measures help predict the outcome of treatment and whether certain behavioral changes can either promote or interfere with weight loss. They will also test whether weight loss causes changes in the behavioral measures. Given the fact that most of the people who lose weight will regain all or most of it, it is extremely important to optimize the treatment of obesity by tailoring weight loss regimens to individual patients.

XIV. Sensory Aids

A. Hearing Impairment

[366] Computerized Adaptive Methods for Selecting Hearing Aids

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Sponsor: VA Rehabilitation Research and Development Service (Project #C432-RA)

Purpose—The introduction of digital technology to hearing health care will have substantial impact for testing auditory theories, the methods by which auditory signals are developed and processed, and eventually on the breadth and flexibility of therapeutic options, such as the design of hearing aids. The experiments conducted in this project utilize new digital technology in order to explore the variables that govern the choice of frequency-gain characteristics preferred by persons with hearing loss. In particular, preferred frequency-gain responses are compared utilizing two- and three-band master hearing aid systems.

Methodology—Previous results made under hearing aid conditions have indicated that similar preference judgments were made with both the two- and three-band systems tested, although some individuals, with steeply sloping high frequency loss, consistently preferred more gain in the mid-frequencies, which was only available with the three-band system. Because of limitations in the master hearing aid (fixed bands, limited gain response in the hearing aid above 4000 Hz, etc.), an advanced system has been developed centered around a personal computer which controls two Ariel boards working simultaneously. The bandwidths can be varied over a wide frequency range and the level within each band can also be varied under tester control.

Using the newly developed master hearing aid system, the effects of varying the cut-off frequencies on the preference judgment were compared for the two- and three-band systems for 10 subjects with

sensorineural hearing loss. The subjects had hearing loss with a variety of audiometric configurations. Loudness growth functions were also developed using a rating system at four test frequencies. Thus, for analysis purposes, it will be possible to relate the effects of the preferred bandwidth characteristics to the loudness judgments and/or the audiometric configuration of the individual subjects.

The experimental procedure was divided into two parts. First, several preferred frequency-gain responses were established, via the simplex adaptive procedure, for various cut-off frequencies which were used to divide the frequency response into two or three independent bandwidths; second, after storing the preferred frequency-gain responses, a round-robin strategy was used to determine the frequency-gain response which was preferred most often from among the previous winners. This procedure was followed separately for the two-band and the three-band systems.

Preliminary Results—Although only 10 subjects have been tested at the present time, several tentative conclusions are apparent. First, the differences in the preferred frequency-gain responses do not differ greatly between the choices made for the two- and three-band systems. Second, there are some exceptions and these occur mainly among the patients with steeply sloping hearing loss, who find the greater flexibility with the three-band system useful. The differences between their choice of frequency-gain responses for the two- and three-band systems are observed in the cut-off frequency chosen for the

low-frequency bandwidth and at the high frequencies where their loss is greatest. In particular, when given the opportunity with the three-band system, they tend to prefer less gain in the high frequencies than available with the two-band system and the cut-off frequency for low frequency band-

width is more closely related to the slope of the audiometric configuration. Third, there is a strong relationship between the levels chosen for the preferred frequency-gain responses and the comfort level obtained from the loudness ratings at various test frequencies.

[367] Variables Affecting Hearing Aid Performance

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Sponsor: VA Rehabilitation Research and Development Service (Project #C337-RA)

Purpose—The goal of this program is to complete electroacoustic and behavioral studies of the interaction of acoustic sound sources with the acoustic impedance of the ear canal and the middle ear.

Progress/Results—A relatively low-cost acquisition system (Rapid Systems, used with an IBM-compatible personal computer) based on the Texas Instruments TMS-32010 signal processing chip was adopted for use. This system allows the user to upload assembly-language routines to the chip. The programming necessary to acquire data with this system is complete and the programming necessary to perform acoustic immittance (impedance and admittance) calculations has been completed.

The software development for data entry and management has been completed. Once the user calls up the program to acquire, a menu appears that calls for the definition of a project. The user can either select an already defined project or can start a new project. Up to 99 projects may be predefined. A dBase database holds this information and prompts the user to give a narrative description of the project and specify the number of conditions. dBase passes the appropriate parameters to the spectral data acquisition routines to prompt the user to initiate the collection of data for these pre-set conditions and, also, to label plots and reports. In addition, parameters such as the sampling rate and number of spectral averages are entered and these are passed to initialize the spectrum analyzer for data collection. Once the user has defined a project, he or she is prompted to enter the data acquisition module. First, demographic data regarding the subject/patient are entered. Through the use of

pointers to records in the raw spectral data files, sets of records can be filtered out for statistical processing.

Development work for using the Rapid Systems as the data acquisition system is completed. Subroutines have been developed locally or modified from routines sold by Rapid Systems. Assembly language routines have been completed to compute auto and cross-power spectra and transfer functions and ultimately the immittance quantities of interest (based on a two-calibration cavity method).

Graphic routines have been implemented in software. The routines prompt the user to select either a two-dimensional plot for data from a single condition (immittance by frequency) or a three-dimensional (3-D) plot (static pressure by immittance by frequency) for either the real or imaginary parts of either the input impedance or the impedance at the eardrum. (In addition, the original transfer function data can be recalled and plotted.) Further, features have been incorporated which allow the user to use default settings for scaling either the immittance or the frequency axis or to self-define the scale or to allow the plot to be auto-scaled. Finally, for 3-D plots, users can shift the view angle.

Measurements of the acoustic impedance of the transducers used in this program have been completed using an computerized adaptation of the two-load method described by Egolf and Leonard. Test-retest data for an ER-3A earphone have been acquired and studies have been conducted on a variety of Knowles electronics earphones. Estimates of impedance quantities (driving point and eardrum) in the frequency range up to 4,800 Hz from the ears of 25 non-hearing-impaired subjects have been

acquired. These data are in good agreement with published data. Studies have been completed which demonstrate that impedance data accurately predict measured sound pressure levels in the ear canal. A three-calibration cavity method has been implemented in an attempt to improve measurement accuracy in the higher frequency region. This method is now undergoing validation.

A third algorithm, which utilizes source impedance data in the equation, is currently being implemented. Studies of the effects of aural pathology, static ear canal pressures, and body position are ongoing.

Recent Publications Resulting from This Research

Effect of Stiffening the Middle Ear on Word Recognition Ability. Cooper W, Larson V, Ball T, ASHA 32(10):117, 1990.

Predicting SPLs in the Ear Canal by Acoustic Impedance Measurement. Larson V, Cooper W, Oliver J, ASHA 32(10):145, 1990.

Validation of an Aural Impedance Measurement System. Larson V, et al. *Audiol Today* 2(2):32, 1990.

Application of Acoustic Impedance Measures to Hearing Aid Fitting Strategies. Larson V, Egolf D, Cooper W, in *Vanderbilt Report II: Amplification for the Hearing Impaired*, G. Studebaker, F. Bess, L. Beck (Eds.), New York: York Press, 1991.

Occluded Ear Simulator with Variable Acoustic Properties. Egolf D, Kennedy W, Larson V, *J Acoust Soc Am* (in press).

[368] DHCP Database and Quality Assurance Information System for Audiology and Speech Pathology

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Sponsor: VA Rehabilitation Research and Development Service (Project #C979-PA)

Purpose—The purpose of this project is to assemble a database and quality assurance information program on mainframe computers used in VA medical centers. Capitalizing on patient information usually entered into medical center computers, three additional and essential elements are required. These are: 1) the speech, hearing, or language problem presented by the patient; 2) the procedure applied in the assessment and treatment of the problem; and, 3) the assessment and/or treatment outcome.

Progress/Methodology—After soliciting end-user preference data and information from 10 VA medical centers, an alpha test version was constructed and developed. This version, written in MUMPS, is centered around problem codes (ICD-9) and procedural codes (CPT) and was released to four medical centers for testing. Based on user input, the design of the package was enhanced and was made ready for beta testing. Reports packages centering around patient visits, patient problems, and patient procedures have been implemented, and complement a variety of recurring reporting requirements of Audi-

ology and Speech Pathology Programs.

Twelve medical centers completed participation in beta testing of the package. After a 60-day trial, the participating sites filed an evaluation of the package. Analyses of the evaluation resulted in minor technical revision of the package and substantial modification of ICD and CPT codes. In addition, interfaces with three other VA DHCP packages are being implemented. One additional release for testing is planned.

A review of the treatment-outcomes literature in speech- language pathology has been completed. This report focused on the measurement of therapeutic change, and functional outcome measures. This information will be considered when implementing the outcome stage of this DHCP package.

Future Plans—Goals for this project are: 1) to implement coding mechanisms for gauging treatment outcome; 2) to consider quality improvement activities based on an "expert systems" approach; and, 3) to release the QUASAR package to all VA medical centers.

[369] Direct Measurement of Loudness Recruitment in Hearing-Impaired Veterans

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Sponsor: VA Rehabilitation Research and Development Service (Project #C296-3RA)

Purpose—This study aims to determine how best to adapt cross-modality matching to the measurement of loudness in a clinical setting.

Progress—Loudness measurements were obtained at a frequency in the region of impaired hearing for 12 people with bilateral cochlear impairments. From this group, test-retest measurements were performed for 11 people with an average hearing loss of 60 dB. Data collection and analysis are continuing. A comprehensive analysis of the scientific findings obtained during the 6 years of this project is underway.

Methodology—All measurements were obtained in a double-walled soundproof booth. The stimuli were tone bursts varying in frequency from 750 to 3700 Hz and lines of light displayed from 35-mm slides. Prior to the loudness measurements, pure-tone thresholds were obtained by the method of limits and by a 2IFC adaptive procedure with feedback. Listening was monaural through a TDH-49 earphone mounted in an MX-41/AR cushion.

Loudness was measured by absolute magnitude estimation (AME), absolute magnitude production (AMP), and cross-modality matching (CMM). The measurements involved two sensory continua: perceived length and loudness. These psychophysical methods enabled the slope of the loudness function (rate of loudness growth) to be obtained in the stimulus region of interest (i.e., within the 4-to-30 dB sensation level range for each AME, AMP, and CMM function). Local slopes were determined individually by using a calculation procedure developed for this purpose.

The within-session stability and intra-individual consistency of the data were assessed by determining the extent of the agreement between the measured and predicted regional slope values. Slopes obtained from AME and AMP of loudness gave the directly *measured* slope values; those derived from CMM and AME of perceived length gave the *predicted*

slope values. Intersession reliability estimates were obtained from test-retest measurements obtained in separate sessions for the same signal frequency.

Preliminary Results—For the group of 11 people tested twice, the measured slope is 2.02 in the first session and the predicted slope is 1.88. The difference of -0.14 gives a measured deviation of -6.9% . The measured slope is 1.85 in the second session, and the predicted slope is 1.94. The difference of $+0.09$ gives a measured deviation of 4.9% . The close agreement between the measured and predicted slope values shows that the within-session data are consistent and stable.

The results thus far also indicate that the slopes remain stable and reproducible between sessions separated by one month or more. For the group as a whole, the measured slope is 2.02 in the first session, and 1.85 in the second, giving a measured deviation of -8.4% . In contrast, the predicted slope is 1.88 in the first session, and 1.94 in the second, giving a measured deviation of 3.2% . As important, the mean slope of 1.9 can be accurately predicted from the empirically determined function relating the slope of the loudness function to the degree of hearing loss.

The slope magnitudes appear robust and stable, as do the loudness settings made by the individual subjects. Across subjects, the intersession difference in levels set in a CMM task is typically about 3 dB. Taken together, these results yield a test-retest reliability coefficient of $+0.91$.

Future Plans/Implications—The analysis of the scientific findings will serve as the basis for the development of a clinical protocol showing how CMM can be applied to routine audiological assessments.

Recent Publications Resulting from This Research

Intensity Discrimination as the Driving Force for Loudness. Application to Pure Tones in Quiet. Hellman W, Hellman R,

J Acoust Soc Am 87:1255-1265, 1990.
 Loudness Relations for Individuals and Groups in Normal and Impaired Hearing. Hellman R, Meiselman C, J Acoust Soc Am 88:2596-2606, 1990.
 Magnitude Scaling: A Meaningful Method for Measuring Loudness and Annoyance? Hellman R, Zwicker E, Invited paper, Fechner Day 90, International Society for Psychophysics, Wurzburg, Germany, 123-128, 1990.
 Variability of the Slope of the Loudness Function in Normal and Impaired Hearing. Hellman R, Meiselman C, J Acoust Soc Am 88:S50, 1990.
 Development of Cross-Modality Matching for Individual Loudness Measurement. Hellman R, Technical Session, American

Speech and Hearing Association, Atlanta, GA, 1991.
 Loudness Measurement by Magnitude Scaling: Implications For Intensity Coding. Hellman R, in Ratio Scaling of Psychological Magnitudes—A Tribute to the Memory of S.S. Stevens, G.A. Gescheider, S.J. Bolanowski (Eds.). Hillsdale, NJ: Lawrence Erlbaum Associates, Inc., 215-227, 1991.
 Predicting the Loudness of Tone-Noise Complexes from Stevens's and Zwicker's Procedures. Hellman R, Invited paper, Noise-Con'91, Tarrytown, NY, 1:491-498, 1991.
 Rate of Loudness Growth for Pure Tones in Normal and Impaired Hearing. Hellman R, Meiselman C, J Acoust Soc Am (in press).

[370] Effect of Presence Versus Absence of Prolonged Amplification on Audition

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Sponsor: VA Rehabilitation Research and Development Service (Project #C578-RA)

Purpose—This longitudinal, prospective, large-sample investigation will examine the effects of a prolonged lack of auditory stimulation through failure to provide amplification on behavioral, neurophysiologic, and electroacoustic measures of audition in adults with sensorineural hearing impairment. Subjects will be followed over a 3-year period. The results of this study will enhance understanding of communicative functioning with binaural versus monaural amplification and contribute to a theory of the effects of long-term lack of auditory stimulation on audition. The results will also contribute to a resolution of the problem of monaural versus binaural fitting. The specific research objectives of this proposed investigation are to: 1) periodically examine, over the 3-year period, the effects of lack of auditory stimulation (absence of amplification) on hearing sensitivity and speech perception and processing; 2) investigate whether a prolonged lack of auditory stimulation (absence of amplification) affects the absolute or interpeak latencies of the early and middle evoked potentials; 3) investigate whether a prolonged lack of auditory stimulation (absence of amplification) affects the threshold of the contralateral acoustic reflex; 4) investigate whether the effects of a prolonged lack of auditory stimulation (lack of amplification) are modified by subject variables at the onset of the study, including degree of hearing impairment, duration of hearing

impairment, age, sex, unaided speech-recognition score, and length of interval between the onset of hearing impairment and date of hearing-aid fitting; 5) investigate whether the effects of prolonged lack of auditory stimulation in the unaided ear of the monaurally-aided persons are influenced by the ear (right versus left) aided; and, 6) determine whether the effects of prolonged lack of auditory stimulation in the unaided ear of the monaurally-aided person can be halted, reversed, or offset by the introduction of binaural amplification.

Progress/Preliminary Results—In the first year of the study (phase I), 155 subjects—an experimental group of 81 subjects with sensorineural hearing loss (48 subjects binaurally aided and 33 subjects monaurally aided) and a control group of 74 normal hearing subjects—were given the following tests:

- *Routine Audiologic Tests.* 1) pure-tone air-conduction thresholds; 2) pure-tone bone-conduction thresholds; 3) speech recognition threshold; 4) static-acoustic middle-ear admittance; 5) tympanometry; and, 6) contralateral acoustic-reflex threshold testing.
- *Speech-Recognition Tests.* 1) speech-recognition for CID W-22 monosyllabic PB words; 2) speech recognition for nonsense syllables; and, 3) speech-recognition in noise for high predictability SPIN.

Sentence (S/N ratio for the 50% recognition to be established using the adaptive procedure).

- **Electrophysiologic Testing.** 1) brainstem auditory evoked potentials; 2) middle-latency auditory evoked potentials testing (though not for all subjects, as some refuse further testing or decline the electrophysiologic testing because of fatigue).

In the second year of the study, 42 subjects—an experimental group of 23 subjects with sensorineural hearing loss (13 binaurally-aided and 10 monaurally-aided) and a control group of 19 normal hearing subjects—were evaluated for the second phase of the study (overall attrition rate was noted to be 15-18%). Although the number of subjects seen so far during the second phase is not sufficient at this time for statistical analyses, the following were noted:

- Three ears among the unaided ears (total 10) showed decrement in the W-22 beyond the 95% confidence interval. One of these subjects demonstrated noticeable increase in the signal-to-noise ratio for the SPIN as well.

- One aided ear among the monaurally aided demonstrated an increase in W-22 beyond the 95% confidence interval.
- No aided ear in the monaurally aided group had demonstrated change in either direction (decrease or increase in the score).
- Two ears among the binaurally aided subjects demonstrated an increase in the W-22 score beyond the 95% confidence interval.

Future Plans—Our plans are: 1) to further expand the number of subjects with sensorineural hearing loss for the first phase (from 82 to 100), 2) to complete the second phase of testing by April-May 1992 so that the third and final phase of the study may begin.

Recent Publications Resulting from This Research

Auditory Deprivation from Monaural Amplification and Recovery. Silman S, Silverman C, presented at the Annual Convention of the International Congress in Audiology, Tenerife, Spain, 1990.

[371] Nonauditory Factors Affecting Hearing Aid Use in Elderly Veterans

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Sponsor: VA Rehabilitation Research and Development Service (Project #C570-RA)

Purpose—Numerous authors have acknowledged the influence of visual acuity, manual dexterity, cognition, motivation, and family support on the hearing aid evaluation, selection, and rehabilitation processes with elderly patients. To date, there has been no rigorous investigation of the predictive value of assessing various nonauditory factors when considering amplification for the elderly. Limited study with a small sample size, as well as much anecdotal evidence, suggests that a large scale, well-controlled study is warranted.

Methodology—Specific aims of this investigation are to evaluate several auditory and nonauditory factors in a group of elderly veterans who are to receive hearing aids through the Department of Veterans Affairs. Each veteran will receive an initial evaluation, which will include the following:

- Assessment of auditory function.
- Assessment of nonauditory factors including visual acuity, fine motor coordination, motivation for improved hearing through hearing aid use, social support, and mental status.
- Completion of the Hearing Handicap Inventory for the Elderly (HHIE).
- Completion of the Sickness Impact Profile (SIP).
- A hearing aid evaluation and selection of appropriate devices.

At one year following fitting and dispensing of the selected hearing aid(s), subjects will be reevaluated in terms of the above assessments.

The key questions of this study are: 1) How do the nonauditory factors listed above affect the use of hearing aids in an elderly veteran population as

measured by changes in the HHIE? 2) Do the auditory factors degree of hearing loss, slope of hearing loss, word discrimination, ear canal resonance, and insertion gain relate to predicting hearing aid success in this sample? and, 3) Does a change in

the HHIE relate to a change in SIP, a standardized measure of functional health status?

Progress—To date, 15 subjects have been entered into the study.

[372] A Prospective Randomized Cooperative Study of Advanced Cochlear Implants

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Sponsor: VA Rehabilitation Research and Development Service (Project #C304-CSP)

Purpose—This study was designed to compare the efficacy and safety of the 3M/Vienna® single-channel and three multichannel cochlear implant devices: Nucleus®, Symbion Ineraid®, and UCSF Storz devices.

Progress/Methodology—The study originally was to include a total of 120 patients accrued from seven participating VA centers over a period of 3 years. An additional 2 years of patient follow-up to determine long-term efficacy is planned for all study patients. Delays in development of the UCSF device have necessitated a change in the study plan. Only three devices were to be studied in 90 patients. In November 1988, the 3M Company withdrew the 3M/Vienna single-channel device from the market. Twenty study patients had been implanted with the device. This decision has resulted in the limitation of treatment assignment to one of two multichannel devices.

Only 80 patients in all will be accrued. Eligible patients include postlingual bilateral profoundly deaf individuals who receive no benefit from appropriate amplification. Patients eligible for randomization must have no radiologic evidence of gross bony overgrowth of the cochlea. Intensive audiologic evaluations will be completed at 1, 3, 12, and 24 months after initial stimulation. Additional yearly assessments of the outcome measures of interest will be completed for each patient until the conclusion of the study.

All required patients were implanted by September, 1989. All implanted patients have received their assigned device with the exception of two

patients who received secondary (single-channel) devices. Since the assigned multichannel device could not be implanted in two patients, two additional patients were randomized, resulting in a total sample size of 82 implanted patients.

Cochlear implantation has been completed without major difficulties or complications. Three patients have been reimplanted—one due to a malfunctioning electrode, one due to severe facial twitch, and one due to breakage of the device pedestal. One device has been explanted at the request of the patient.

Recently, the Cochlear Corporation, manufacturer of the Nucleus device, has developed a new speech processor for its implant. The new processor is lighter and smaller and uses a new multi-peak coding strategy that is expected to improve hearing over that of the original processor. The new equipment is now being supplied as the standard processor for use with the Nucleus device. All Nucleus study patients are being offered this new processor immediately following their 2-year evaluation. Patients return after using the new processor for 3 months and are retested so that the efficacy of the new processor may be evaluated. This additional evaluation will provide outcome data using the newer Nucleus 22-channel system as well as the original Nucleus processor for comparison with other study devices.

Preliminary Results—Patient follow-up is proceeding well. Current data clearly document the benefit of cochlear implantation. Quality-of-life measures suggest that patients are pleased with the effects of

cochlear implantation. With the increasing amount of available patient data, differences among treatment groups are emerging.

Recent Publications Resulting from This Research

A Prospective Randomized Cooperative Study of Advanced Cochlear Implants (Abstract). Cohen NL, Second Interna-

tional Cochlear Implant Symposium, Iowa City, IA, 1990. Use of Principal Components Analysis to Develop a Composite Score as a Primary Outcome Variable in a Clinical Trial. Henderson WG, et al., *Controlled Clin Trials* 11:199-214, 1990.

Prospective Randomized Clinical Trial of Advanced Cochlear Implants: Preliminary Results of a Department of Veterans Affairs Cooperative Study. Cohen NL, Waltzman SB, Fisher SG, *Ann Otol Rhinol Laryngol*, October 1991.

[373] Early Detection of Hearing Loss from Ototoxic Agents by High-Frequency Auditory Evaluation

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Sponsor: VA Rehabilitation Research and Development Service (Project #C227-RA)

Purpose—This is an ongoing multisite study including four VA Medical Centers. The primary study goal is to serially monitor the hearing of patients during treatment with potentially ototoxic agents to determine if ototoxicity is detectable in the high frequency range (>8 kHz) prior to the conventional frequency (≤ 8 kHz) range of hearing. Early warning of impending, communicatively handicapping hearing loss should result, allowing health care professionals to examine possible treatment alternatives. Secondary goals relate to the ototoxic process (progression, direction, and recovery of threshold change) and to individual patient baseline variables (e.g., age, disease state, pre-existing hearing loss). Study drugs include the aminoglycoside antibiotics amikacin, gentamicin, and tobramycin, and the chemotherapeutic agent, cisplatin.

Progress/Methodology—A computer-based audiometer and immittance system is being utilized by all sites for data collection. The audiometer has been shown to provide valid and reliable intra- and intersession pure-tone threshold results with normal-hearing individuals. Computer technology was selected because of the large geographic distances of the remote sites from the central site and the extensive data management requirements of a multisite research protocol. A software program to manage the overall research project was custom designed with three main functions: 1) to facilitate peripheral-site data management; 2) to provide electronic transfer of peripheral-site data to the

central-site database; and, 3) to consolidate and categorize all data at the central site for analyses. The program allows for automated statistical analyses at the central site by the study biostatistician.

Initial study inclusion criteria include: ≥ 4 days of drug administration, negative auditory pathology, baseline audiogram obtained prior to or within 72 hours following initial aminoglycoside dose and 1 week prior to or within 24 hours following initial cisplatin dose, and baseline hearing thresholds of ≤ 70 dB SPL at 10 kHz and 80 dB SPL at 12 kHz. A limited number of veteran patients meet this original hearing threshold criteria; therefore, entry requirements have been altered to include baseline thresholds ≤ 100 dB SPL at 10 and 11.2 kHz in at least one ear. Subjects are tested serially during drug administration with two follow-up evaluations. A minimum of three audiograms is required for inclusion in data analyses.

Preliminary Results—To date, 5,891 patients have been screened. Of these, 101 (172 ears) have met criteria and completed three or more tests: 64 aminoglycoside-treated subjects (113 ears), 25 cisplatin-treated subjects (40 ears), and 12 control subjects (19 ears). Preliminary analysis revealed negative (poorer) hearing threshold changes in 55% ($N=62$) of those receiving aminoglycosides and in 83% ($N=33$) receiving cisplatin. Overall, hearing changes occurred initially in the high frequencies (≥ 8 kHz), or in both the high and low frequencies, in 84% of those individuals who showed hearing

changes. Patients treated with cisplatin appear to reveal more significant hearing threshold changes than those treated with aminoglycosides. Overall, control subjects have revealed hearing threshold stability throughout testing, suggesting that ill but responsive hospitalized patients can be tested reliably.

Future Plans/Implications—Current preliminary findings support the use of serial high-frequency auditory monitoring of patients being administered potentially ototoxic medications. Furthermore, current data analysis has identified a range of five frequencies, specific to each individual, which may be highly sensitive to ototoxic change. It appears that this statistical grouping of high frequencies will require much less time than complete audiometric protocols while providing a very high percentage of

ototoxic identification. More data are required to publish preliminary findings on the secondary goals regarding the specific auditory processes involved in ototoxicity. The ultimate goal is to prevent communicatively handicapping hearing losses in patients who are at risk from treatment with potentially ototoxic agents. Intervention studies to examine alternative treatment protocols that minimize ototoxicity are a natural extension of this research.

Recent Publications Resulting from This Research

Managing a Multisite Research Program with Microcomputer-Based Communications. Fausti SA, et al., *Comput Users Speech Hear (CUSH)* 7(1), 1990.

Reliability and Validity of High-Frequency (8-20 kHz) Thresholds Obtained on a Computer-Based Audiometer as Compared to a Documented Laboratory System. Fausti SA, et al., *J Amer Acad Audiol* 1:162-170, 1990.

[374] Measurement and Prediction of Benefit from Amplification

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Sponsor: VA Rehabilitation Research and Development Service (Project #C344-3RA)

Purpose—The goals of this project are to determine the amount of benefit received from hearing aids in everyday life and to develop methods of quantifying and predicting hearing aid benefit for elderly listeners.

Progress—Investigations completed within the past year include: 1) a study of the maturation of hearing aid benefit in elderly persons who are acquiring their first hearing aid and in experienced hearing aid users who are obtaining a new instrument; 2) assessment of the reliability of self-report hearing aid benefit using the Profile of Hearing Aid Benefit (PHAB); 3) evaluation of the relationship between PHAB scores and adaptation to hearing loss; and, 4) comparison of three hearing aid follow-up management procedures in terms of their affect on short- and long-term hearing aid benefit.

Investigations in progress include: 1) study of the relative importance of hearing loss, audiogram slope, signal-to-babble ratio, speech level, and low-, mid-, and high-frequency audibility changes in determining hearing aid benefit; 2) study of spectral and temporal resolution as a function of level in

normal hearers, and development of a procedure for measuring this in hearing-impaired listeners; and, 3) evaluation of the effect of response mode in determining the outcome of the PHAB inventory.

Results—To evaluate the maturation of hearing aid benefit, benefit was measured soon after the hearing aid fitting and again after 10 weeks of adjustment to hearing aid use. Both objective and subjective measurement procedures were used. In noisy or reverberant listening environments when visual cues were available, changes in benefit were small or zero. However, in a low-noise setting and in a noisy setting without visual cues, improvements in benefit were seen over time. The relationship between long-term subjective and objective benefit data was evaluated. Significant, but modest, correlations were found between objective and subjective data for low-noise and reverberant listening environments. Comparison of experienced and naive hearing aid wearers suggested that, although experienced wearers obtain more benefit than naive wearers, they evidence similar time-related changes in benefit during the first 10 weeks of new hearing aid use.

Results from experienced hearing aid wearers indicated that self-assessed benefit was significantly related to magnitude of reported unaided difficulties for all seven PHAB subscales. In addition, one of three scores evaluating adaptation to hearing loss contributed to benefit prediction for the two sound perception subscales of the PHAB.

Test-retest reliability of PHAB subscale scores was found to be consistent with previous studies but, nevertheless, quite modest. Critical differences were fairly large compared with the anticipated size of benefit differences due to, for example, different hearing aid prescriptions. It is concluded that the PHAB is best suited for group research.

Recent Publications Resulting from This Research

- Accuracy of Audiometric Test Room Simulations of Three Real-World Listening Environments. Cox RM, Alexander CG, Rivera I, *J Acoust Soc Am* 90:764-772, 1991.
- Comparison of Objective and Subjective Measures of Speech Intelligibility in Elderly Hearing-Impaired Listeners. Cox RM, Alexander CG, Rivera I, *J Speech Hear Res* 34:904-915, 1991.
- Comparison of Two Questionnaires for Patient-Assessed Hearing Aid Benefit. Cox RM, Gilmore CG, Alexander GC, *J Am Acad Audiol* 2:134-145, 1991.
- Hearing Aid Benefit in Everyday Environments. Cox RM, Alexander GC, *Ear Hear* 12:127-139, 1991.
- Preferred Hearing Aid Gain in Everyday Environments. Cox RM, Alexander GC, *Ear Hear* 12:123-126, 1991.

[375] Studies on Amplification Selection for the Hearing Impaired Veteran

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Sponsor: VA Rehabilitation Research and Development Service (Project #C307-2RZ)

Purpose—The purpose of this study was to evaluate the reliability and validity of different hearing aid selection procedures: the revised National Acoustics Laboratory (NAL-R) method, the Memphis State University method and the POGO-II method. A modified version of the traditional Carhart comparative speech testing method was also examined on a limited number of subjects. The data collected will allow us to evaluate: 1) changes in user satisfaction and measured performance over a one-year period following the hearing aid fitting; 2) the correspondence between laboratory measurements and the results of questionnaire data; 3) the correlation between behavioral thresholds, real ear *in situ* responses and the results of electroacoustic analysis in a 2cc coupler; and, 4) factors which might influence ultimate user satisfaction with a hearing aid, such as certain audiologic patterns or the presence of other disabilities.

Methodology—Fifty patients were placed into each of the different selection protocols. Prior to the purchase of hearing aids and at periodic intervals thereafter, each subject and a "significant other" were administered a series of questionnaires including the Hearing Performance Inventory (HPI revised), the HHIE-S, and the Hearing Aid Perfor-

mance Inventory (HAPI). The screening was also performed for both visual and mental disabilities.

Hearing aid fitting and evaluations followed the protocol pertinent to the particular selection procedure. A FONIX 6500 real ear measurement system was used to verify the spectrum of the aided signal delivered to the eardrum. Once the hearing aids were adjusted to approximate closely the desired response, the Speech Perception in Noise (SPIN) test and the Nonsense Syllable Test (NST) were used to indicate improvement in speech intelligibility. Behavioral measurements of functional gain were also obtained. Subjects returned at approximately 1-month, 6-month, and 1-year intervals following the hearing aid fitting. At these sessions, laboratory measurements were obtained again.

Results—Prescribed (target) gain curves were calculated for those patients fit with the NAL or COX prescriptive gain formulas. All were fit with in-the-ear (ITE) hearing aids. Trimpots for both tone and output control were ordered on all hearing aids to afford greater flexibility in the fitting process.

The data do not provide strong support for using any one of these prescription formulas over another when fitting conventional analog ITE hearing aids, given that the degree of fitting error is

nearly as large as the difference between prescribed gain.

The data do support the concept that real ear measurement is preferable to 2 cc coupler fitting in order to account for individual differences in canal resonance and impedance.

At the follow-up visit that is scheduled at approximately 30 days after each hearing aid fitting, each patient is instructed to adjust the volume wheel of his hearing aid so that it is at a most comfortable listening level for running speech presented at a conversational level (60 dB SPL). The non-test ear is plugged or muffed during testing, and each ear is tested individually for binaural fittings. Electroacoustic analysis of the hearing aid at this comfort setting is obtained for comparison with electroacoustics of the hearing aid at the volume wheel setting that was previously used to match prescribed gain as closely as possible (real ear measurement).

Comparison of high-frequency average (HFA) gain values under these two conditions indicates that most of the subjects preferred, after this initial

month of experience with amplification, somewhat less gain than was originally prescribed (median - 5dB). In a few cases, however, the comfort volume wheel setting actually resulted in up to 5 dB more HFA gain than had been prescribed. These data emphasize the fact that, since any prescription gain formula is considered only a first approximation to the "best" amplification parameters, it is imperative that a fitting procedure include follow-ups over time during which adjustments can be made in the amplification settings.

These results provide important information regarding the adequacy of current selection and fitting methods for amplification systems, and regarding the direction in which future research and development should proceed. We are currently analyzing the questionnaire data, which will provide information about the perceived benefit of amplification from both the hearing aid user's and family member's perspectives, and the speech intelligibility data, which will allow the evaluation of the accuracy of the modified speech transmission index for predicting user-benefit from hearing aids.

[376] Development of a Digital Hearing Aid and Computer-Based Fitting System

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Sponsor: VA Rehabilitation Research and Development Service (Project #C203-2DA)

Purpose—The purpose of this project is to develop a new hearing aid concept and a companion hearing assessment and fitting procedure that will lead to improved performance of acoustic amplification for hearing-impaired people.

Methodology—Digital implementation provides greater fitting precision and flexibility with which to match the patient's hearing impairment. With digital implementation, the instrument can be connected to the fitting system and control and monitor the aid while the patient is wearing it. Therefore, the variability associated with earmold acoustics and head diffraction can be directly accounted for in fitting the aid. Digital implementation makes it

possible to utilize adaptive filters for controlling gain and frequency response and for suppression of noise and feedback.

Results—Work this year has focused on completing the VLSI chip designs and on the development of a wearable field evaluation unit. Features of the wearable unit, which operates for 20 hours with four penlight cells, include four channels of filtering with adaptive compression, feedback equalization, and noise reduction. These are the same features that have been shown to be beneficial in laboratory tests with hearing-impaired subjects.

A subject was fitted with the first unit on September 16, 1991. The wearable unit has four

programmable memories which can be configured with linear or nonlinear amplification. Furthermore, feedback equalization and noise reduction can be either active or nonactive. The fitting environment is controlled from an IBM PS-2 computer. Programming the aid and verifying the fits using a real-ear measurement system is controlled through four windows: a client description window, a fit window, a real-ear measurement window, and a program set window.

For the initial trial, memory A was configured to provide linear amplification according to the NAL threshold-based prescription formula. Memory B was configured to provide linear amplification that was shown to be preferred by the subject when listening to soft speech during earlier tests with the bench-top (BT2) system. It provided approximately 7 dB more gain than NAL between 750 Hz and 2000 Hz. Memory C was configured to provide nonlinear amplification. The gain of the aid adapted as a function of input signal level, providing more gain for soft input levels and relatively less gain for loud input levels. The adaptive parameter settings were based on previous data obtained with the benchtop system. Memory D was configured to match the REAR of the subject's own aid. All gains were verified in the subject's ear canal using a probe tube microphone system. The probe tube was inserted to a depth of 32 mm with respect to the antitragal notch.

The subject was asked to use all four settings

while listening to a female talker recite the "Rainbow Passage." The most striking subjective comments were obtained when the subject was listening to loud (75 dBA) connected speech in noise. The linear aid that provided the most gain (setting B) was consistently rejected except when listening to soft speech. The adaptive setting (setting C) was preferred for loud speech, since the speech was intelligible and the background noise was less at the reduced gain. This finding was repeated outside the building when the subject used the aid to converse against a background of highway noise. Setting C was also preferred for this subject when listening to the sound of crinkling paper. The sound quality of the "crinkle" was less irritating than with the linear settings. Setting D was preferred when listening in quiet to moderate and loud speech (i.e., when audibility was not an issue). Settings B and C were preferred when listening to soft speech in quiet. These settings were preferred because they provide more gain than A and D. Overall, settings C and D were rated more highly than settings A and B. Given that the majority of real-world listening environments include background noise and dynamically varying signal levels, it seems that the adaptive processing of setting C will provide the most useful amplification configuration for a wide variety of listening conditions. This hypothesis and other issues will be examined during future field trial studies.

[377] Basic Mechanisms and Rehabilitative Strategies for Presbycusis

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Sponsor: VA Rehabilitation Research and Development Service (Project #C251-3RA)

Purpose—We are studying three basic issues in aging and hearing loss: 1) central versus peripheral aspects of presbycusis; 2) differences in normal aging of the cochlea as a function of gender; and, 3) peripheral influences on maintenance of central processes. We now have anatomical and physiological evidence suggesting that the quail auditory system may provide a singular opportunity for studying "neural presbycusis." Further, because of

the unique potential for hair cell regeneration within the quail cochlea, it offers a special chance for studying the interaction of peripheral reactivation (as with amplification or implant after hearing loss) on maintenance of the central auditory system. Finally, it seems that quail exhibit a gender difference with regard to the accumulation of lipofuscin in the inner ear as a function of chronological aging.

Since humans exhibit a gender difference in the pattern of hearing loss with aging, this histological finding may provide some clue as to its anatomical basis.

Progress/Results—We have determined that the histopathological basis for “presbycusis” in *Coturnix* quail is similar to that of neural presbycusis in man. We are now ready to discover what the electrophysiological correlates of this histopathology may be. In our first set of experiments, we will review auditory evoked potentials in young and old animals in terms of: 1) latency, 2) input-output, and 3) spectral content. Preliminary evidence reveals a slight interpeak wave latency increase with age in the quail brainstem evoked potential. Latency-intensity functions are not parallel and therefore are consistent with sensorineural hearing loss with age. Input-output functions from 11 young and 6 old quail reveal no difference in Wave I amplitude as a function of age, even though ganglion cell number are significantly reduced in the older animals.

In our second experiment, we are examining the accumulation of aging pigment in the inner ears of birds as a function of gender and cell type. Area, density, and number of lipofuscin granules are measured using digitized morphometry of TEM sections of hair cells throughout the cochlea. Preliminary results reveal that for both male and female quail, the density, size, and number of lipofuscin granules is greater in short hair cells. In general, female quail show a greater accumulation of lipofuscin than male quail of the same age. These results provide a first indication of potential differences in sensory cell aging and gender differences within the avian basilar papilla.

Finally, in our third experiment, we are using the regenerative potential of hair cells within the quail as a tool to study the influence of peripheral restimulation on central maintenance. Specifically,

our third experiment will compare the histological impact of peripheral restimulation (hair cell regeneration) with no peripheral stimulation (cochlea removal) on the Eighth Nerve and central auditory pathways. The prediction is that regeneration will maintain central processes while the lack of peripheral input will result in Eighth Nerve and central auditory system degeneration. Clinically, such experiments should provide insight into the long-term effects of permanent hearing loss on the central auditory pathways. Further, they will give some indication of the necessity of providing peripheral stimulation (i.e., auditory prosthesis such as hearing aids or cochlear implants) in order to maintain or prevent degeneration of central auditory pathways.

Implications—The proposed experiments are likely to provide insight into neural presbycusis; a form of presbycusis heretofore defined only theoretically. Further, they will provide a possible histological correlate of known gender differences in the development of human presbycusis. Finally, they will give clues as to the interaction of peripheral restimulation of the cochlea on the maintenance of central auditory pathways.

Recent Publications Resulting from This Research

- Differences in Hearing Aid Gain as a Function of Age. Ryals BM, Auther LL, Hear Instrum April 1990.
- Hair Cell Regeneration in Senescent Quail. Ryals BM, Westbrook EW, Hear Res 50:87-96, 1990.
- Hair Cell Re-Innervation after Acoustic Trauma in *Coturnix* Quail (Abstract). Ryals BM, Westbrook EW, Spencer RF, Assoc Res Otol 14:338, 1991.
- Issues in Neural Plasticity as Related to Cochlear Implants in Children. Ryals BM, Rubel EW, Lippe W, Am J Otol (suppl), 12:22-27, 1991.
- Changes in the Acoustic Nerve after Hair Cell Regeneration. Ryals BM, et al., Exp Neurol (in press).
- Hair cell Regeneration in the Chicken Cochlea Following Aminoglycoside Toxicity. Lippe WR, Westbrook EM, Ryals BM, Hear Res (in press).
- Regeneration of Vertebrate Sensory Receptor Cells. Ryals BM, Ciba Foundation Symposium No. 160 (in press).

[378] Natural Language Processing Principles for Improving Deaf Writing

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Sponsor: National Science Foundation; Nemours Foundation

Purpose—The goal of this project is to develop a computer tool to correct the written English of deaf writers. The envisioned program will accept and analyze a written document and provide corrective advice when an error is found. Essentially, the system will act as an English tutor that will help deaf individuals improve their English writing skills.

Methodology—The design of this program is based on the belief that English should be viewed as a second language for many deaf people and that errors in the written English of deaf writers arise due to language transfer (LT) coupled with the relative lack of exposure by the individual to English. We are designing this program so that it will take advantage of the writer's knowledge of American Sign Language (ASL) in identifying errors and suggesting corrections.

Linguists have found evidence of LT between spoken languages. Based on these findings, we believe it is reasonable to expect LT from ASL (a visual-gestural language) to English (a spoken language). Our work is driven by analysis of writing samples based on the research in LT. This analysis will lead to a taxonomy of errors.

The system itself will consist of two phases. In the first phase, the system will identify errors. To do this, it relies on a grammar of English which has been augmented with a set of error rules which

capture the errors in our taxonomy. The second phase of processing will generate a correction.

Progress—The majority of the work to date has been devoted to analyzing writing samples from deaf individuals with an ASL background in order to develop the error taxonomy. In addition to this, we have implemented a prototype system that contains an extensive grammar of English which has been augmented with a number of error rules (both syntactic and semantic). The system can use these rules in order to identify a subset of the sentence level errors identified by the sample analysis.

Results—Of major and continuing focus in this project is the correction of errors that result from LT at the discourse level. It has been documented that much of the language instruction of the deaf has concentrated on the sentence level, and thus deaf students may reach the point where their writing lacks discourse cohesion even though the individual sentences are grammatically correct. Therefore, the correction of discourse level errors should be particularly useful for many deaf writers. Our current work investigates models which can identify such discourse errors. In addition to this, work has begun on the correction phase of processing which must be tailored to the individual user.

[379] Feature Extraction Methods for a Video Telephone for Deaf and Hard-of-Hearing People

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Purpose—In order for deaf and hard-of-hearing people to communicate over residential telephone lines using sign language, methods are being devel-

oped to significantly compress the information in a video signal in order to meet the severely limited bandwidth requirements of the telephone system.

This visual telephone provides an alternative to the TDD for those deaf and hard-of-hearing people who prefer to sign.

Progress—Intelligibility studies were performed at Gallaudet University involving 120 deaf adults as human subjects in order to determine the minimal frame-rate needed for intelligible signing. Methods of compressing the feature-extracted images has continued.

Methodology—In order to transmit video information in real-time over residential telephone lines, the video data must be compressed on the order of a 1000:1 ratio. The bulk of this compression is done by performing a feature-extraction on a video image. This feature-extraction method extracts the outlines of the hands, arms, torso, head, and facial features, creating a line-drawing of the signer. This line-drawing would then be further compressed and transmitted over the telephone lines using a 19.2 kbaud modem at a rate of approximately 10 frames per second. These line-drawings are then animated at the receiving end, providing a moving representation of a person signing.

Results—The results of the intelligibility study showed that more than 90% of the signs were intelligible even at frame rates as low as 6 frames per second. The intelligibility scores for finger-spelling were considerably lower. Finger-spelling at "fast" rates of 240 characters per minute was minimally intelligible, even at high frame rates, while "slow" finger-spelling rates (100 characters per minute)

yielded intelligibility scores nearly equal to those achieved for signs at frame rates up to 10 frames per second. Intelligibility decreased significantly at lower frame rates.

Two promising approaches have been developed to meet the projected bandwidth of 19.2 kbaud at 10 frames per second, or 1,920 bits per frame. The first, called Zero-Quadtree (ZQT), is a lossless method which compresses the images to approximately 3,050 bits per frame. Another method, called Heuristic Chaining (approximately 5% loss) compresses the images to approximately 2,830 bits per frame.

Future Plans—Further intelligibility studies are being conducted using a mock two-way setup, allowing two people to have an actual conversation using this system. These tests are being conducted in order to determine what human factors issues need to be addressed before this technology can become a commercial product.

Further compression techniques need to be developed to reduce the data rate by another 50% in order to meet the projected bandwidth of 19.2 kbaud at 10 frames per second.

Recent Publications Resulting from This Research

Parallel Methods of Feature Extraction for Low Bandwidth Transmission of Sign Language. Galuska S, Master's thesis, University of Delaware, 1990.

Intelligibility Experiments with a Feature Extraction System Designed to Simulate a Low-Bandwidth Video Telephone for Deaf People. Harkins J, et al., in Proceedings of the 14th Annual RESNA Conference, Washington, DC, 38-40, 1991.

[380] Auditory Redundancy for Hearing-Impaired Individuals

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Sponsor: National Institute on Disability and Rehabilitation Research; Association of Data Processing Service Organizations

Purpose—Currently, people with hearing impairments have little or no difficulties in using computers. The use of sound as a standard feature has been minimal, usually no more than a beep. If the beep is accompanied by some visual event, no problem is encountered. If the beep is not accompanied by a visual event, the deaf person may miss the cue, may

deduce what change or error has occurred, or may use a simple sound alert device with a flashing light to detect the sound.

However, the increasing sophistication of synthetic and digital speech technologies has made it easier and more desirable for computer companies to consider incorporating voice output into their

products. This would probably take the form of standard voice features in the operating system (such as voice output of error messages) or available voice features that could be "called" from the operating system by application programs.

As a first step in addressing these problems, a proposal has been made for the incorporation of a "ShowSounds flag" in standard computer operating systems. Such a flag would appear along with other control settings for the operating system. The flag would provide a means for the user to signal cooperating software and operating systems when the user cannot hear any sounds emitted by the computer. Programs and operating systems could then accompany any beeps with some type of visual event on the computer screen. The ShowSounds flag also presents the possibility of "closed captioning" for computer programs.

Methodology—The implementation of the recommendations could be carried out in stages—in fact, it would need to be, since later stages require built-in text-to-speech capabilities that are not yet a standard part of any computer operating system. The stages for implementation would be:

- inclusion of a ShowSounds flag in the control settings of the operating system;
- implementation of visual events to correspond to

beeps triggered by the operating system;

- provision of closed captions for any voice or complex sound events necessary for use of the operating system;
- provision of closed captioning tools for use by third-party developers;
- provision of auto-captioning capability.

In addition, application programs can begin to check for the ShowSounds flag and provide visual cues to any auditory events.

Progress—The proposed ShowSounds flag has been moved forward in three ways. First, the Trace Center has had discussions with Apple computer regarding the inclusion of a ShowSounds flag as a part of their standard control panel for sounds in future versions of their operating system. Second, a ShowSounds feature was incorporated into the AccessDOS software package developed at the Trace Center. AccessDOS provides several important disability access features to IBM PC and PS/2 computers running DOS. The program is distributed free of charge by IBM. Third, the Trace Center has recently entered into an agreement with ADAPSO, a software developers association, to create a set of software application program design guidelines. One of the guidelines deals specifically with the support of a ShowSounds flag by application programs.

[381] Accessibility of TDDs for Hearing-Impaired Individuals with Multiple Impairments

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Purpose—For many individuals with hearing impairments, use of a Telecommunication Device for the Deaf (TDD) is the only means of access to telephone communication. There is a substantial population of hearing-impaired individuals who have other impairments that either hamper their use of a TDD or make use of the TDD impossible for most practical purposes. These other impairments can include language impairments, cognitive impairments, or physical impairments.

Methodology—The project has three phases. First, a meeting was held to identify major issues in phone communication access as they affect individuals with multiple impairments. On November 12, 1990, a group of 16 people met, representing researchers, TDD users, deaf educators, the TDD industry, and clinicians whose clients have multiple impairments. The group developed a list of 65 problems and potential solutions in the area of telecommunications access. The annotated list has been sent out to

those who attended the meeting for additional ideas and comments.

The second phase of the project is the development of several papers addressing modification of TDDs to improve accessibility and the use of computers and modems for telephone communication. Five papers are currently planned, covering keyboard enhancements and modifications, alternate and modified input systems, alternate output forms, simplified access to TDD options, and use of computer modems together with special computer access hardware and software. A portion of each document will be devoted to technical information for manufacturers who might want to design equipment incorporating specific accommodation features. The papers will be circulated to TDD manufacturers and organizations for people with hearing impairments, as well as being presented at appropriate conferences.

The third phase of the project will be the

development of a software system for telephone communications using a computer and a TDD-compatible modem. The software will: 1) make it easy for those with little or no computer experience to use the computer for telephone communication; 2) allow the use of existing off-the-shelf computer adaptations for users with physical impairments; and, 3) provide a non-alphanumeric system for communication that can be used by people who have limited or no reading and spelling skills.

Progress—The first phase of the project is in the review phase. The meeting has been held, and the resulting list of suggestions sent out for comment. The second phase of the project has begun, with the first two publications currently in draft form. The third phase of the project is in the early design stages, with different strategies for designing and encoding picture symbols being discussed.

[382] Visual Speech Display as an Articulation Training Aid for the Deaf

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Sponsor: *National Science Foundation*

Purpose—The objectives of the project are to investigate and optimize methods for extracting speaker-independent acoustically-based speech parameters that are closely related to the phonetic content of speech, and to use these parameters to implement a real-time visual display as a flexible speech articulation training aid for the hearing impaired. The visual speech training aid is primarily directed toward improving production of segmental speech features such as vowel and consonant production. New methods for extracting and displaying speech parameters were investigated and tested. Computer-based displays have been implemented for vowel training.

Progress/Methodology—The signal processing for the speech training system was implemented in real-time using a digital signal processing (DSP) coprocessor board. Although the conversion to the DSP system (versus a previous analog implementa-

tion) required somewhat more effort than was originally anticipated, the real-time front end signal processing has now been completed. The digital approach has enabled refinements in acoustic feature computations, thus providing a more consistent and accurate mapping of vowels to a display space.

Discrete Cosine Transform Coefficients (DCTCs) were chosen as the basic acoustic features for encoding speech spectra. The DCTCs are computed as the discrete cosine transform of the nonlinearly scaled speech spectrum and thus represent the global spectral shape. Since the DCTCs were to form the foundation for our visual speech display, it was crucial to verify that the DCTCs contain the majority of acoustic speech information and that the DCTCs compare favorably with formants, another acoustic feature set for vowels. Therefore, we conducted a series of experiments designed to optimize the details of the computations of the DCTCs and to compare the performance of

DCTCs versus formants for automatic recognition. These experiments show that DCTCs, after optimization, give better automatic vowel recognition than do formants. All the knowledge gained from the optimization experiments has been incorporated in processing for the real-time display.

The DCTC acoustic features mentioned above are converted to visual display parameters using a combination nonlinear/linear transformation. The transformation is "trained" using acoustic vowel data collected from normally speaking subjects. Three basic displays have been developed. In the moving object display, an elliptical target region is drawn on the computer monitor for each training vowel. As a speaker utters a vowel sound, our signal processing algorithm continuously moves and scales a basketball according to the computed position in the 2-D vowel display space. The display thus provides immediate, continuous, and easy-to-interpret visual feedback for vowel identity. For the bar graph display, one bar position is depicted for each vowel. As the trainee talks, the display indi-

cates the "amount" each vowel is produced. Finally, vowel productions can be used to control game action in a "Pac-Man"-style game. Four vowels can be selected by the user to control four directions of movement of a game icon.

Preliminary Results/Future Plans—Informal testing conducted to date indicates that hearing-impaired speakers can use the visual speech display to improve their vowel productions. Our primary goals for the upcoming year are to conduct additional tests of the speech display and to use the results of these tests to further refine the display implementation.

Recent Publications Resulting from This Research

Vowel Articulation Training Aid for the Deaf. Zahorian SA, Venkat S, in Proceedings of the International Conference on Acoustics, Speech, and Signal Processing, 1121-1124, 1990.
Vowel Training Aid for the Hearing Impaired Using the TMS320C25. Zahorian SA, Beck AE, in TMS320 Educator's Conference Proceedings, 121-135, 1991.

B. Speech Impairment

[383] Hierarchical Computerized Language Treatment for Aphasic Adults

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Purpose—Recent reports imply that microcomputers may be effective in providing language treatment for aphasic adults. The current project is based on earlier work by the investigators, and expands the use of complex algorithms and hierarchically arranged tasks to deliver language treatment appropriate for the level of severity of each patient. The purpose of the study is to develop hierarchically arranged reading and writing treatment software and test its effectiveness by comparing improvement in patients who receive computerized language treatment with that of patients who receive computer-stimulation ("non-language" activities), or no treatment.

Progress—Reading and writing treatment software has been written, coded, tested, and debugged. Reading (C-CAT/R) and writing (C-CAT/W) tests have been written and test-retest reliability measured. Over three-quarters of our projected subject sample is currently enrolled or has completed a 6-month participation. Statistical analysis has been applied to the results thus far.

Methodology—The project objectives are completed in two phases: During Phase I, the computerized treatment and evaluation material was developed. During Phase II, data is collected through repeated testing of 20 computer-treatment subjects, 20 com-

puter-stimulation subjects, and 20 no-treatment (control) subjects. Data collection in Phase II will take approximately 40 months. The statistical analysis used to evaluate the efficacy of the computer treatment will be a repeated measure analysis of covariance in which two covariances are used, language severity and months post-onset at entry. Changes over time will be evaluated with a repeated measure analysis of variance that includes the pre-treatment scores. Additional analyses will also be conducted including influences of type of aphasia on improvement, and individual patient performance on each treatment task by examining time-series design data.

Preliminary Results—Test-retest reliability measures have been completed for the C-CAT/R and C-CAT/W. Results after 6 months of data collection, with 43 subjects making up the Reading Treatment Group, Stimulation Group, and No-Treatment Group indicate that: computerized language treatment can be administered with minimal assistance by a clinician; improvement on the computerized reading treatment tasks generalized to improvement in non-computer language performance; improvement resulted from the specific language content of

the software and not simply the stimulation provided by the computer; and, chronic aphasic patients can improve performance through computerized treatment. Data for all groups, including the Writing Treatment Group, are still being collected.

Future Plans/Implications—Additional patients are being recruited and assigned randomly to the three groups. The results of the investigation should demonstrate whether computerized reading and writing treatment for chronic aphasia is effective and whether this type of treatment can be administered by a computer with minimal assistance from a clinician.

Recent Publications Resulting from This Research

Intelligent Computerized Treatment or Artificial Aphasia Therapy? Katz RC, *Aphasiology* 4:621-624, 1990.

A Comparison of Computerized Reading Treatment, Computer Stimulation, and No Treatment for Aphasia. Katz RC et al., in *Clinical Aphasiology*: Vol. 19, T.E. Prescott (Ed.), Austin, TX: Pro-Ed, 243-254, 1991.

Computerized Hierarchical Reading Treatment in Aphasia. Katz RC, Wertz RT, *Aphasiology* (in press).

Microaphasiology and the Computerized Clinician. Katz RC, Wertz RT, in *Clinical Aphasiology*: Vol. 21, M.L. Lemme (Ed.), Austin, TX: Pro-Ed (in press).

[384] Computer-Assisted Speech Evaluation Expert System

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Sponsor: VA Rehabilitation Research and Development Service (Project #C468-RA)

Purpose—Diagnostic evaluation of speech requires analysis of speech deviance and speech-related physiological performance. Despite progress in the laboratory, clinical application of new information and technologies has been slow. Present methods are subjective and highly variable. This research program is devoted to developing and testing specific computer and instrumental procedures to measure aspects of speech and speech-related function in subjects with disordered speech. Software is being developed to extract and analyze acoustic, aerodynamic, and physiologic data during connected speech and specific diagnostic maneuvers. Expert systems are being developed to provide interpretation of obtained speech deviance profiles and pro-

vide advice regarding optimum sequencing of diagnostic tasks.

Progress—Work has focused on expansion and refinement of user interface and development and validation of additional protocols for quantitative analyses that result in objective measures of speech and related physiological performance. Initial development stages for the expert system have been completed. A total of 10 diagnostic protocols have been developed for use with 80386 computers and selected analog instruments. Seven protocols provide useful diagnostic information based on acoustic information alone. Additional protocols are structured in increments of increasing invasiveness and

required equipment. Objective acoustic measures of voice, nasal resonance, and prosody are obtained from monologue speaking or maneuvers designed for in-depth measurement of a specific speech parameter. Other protocols employ nonspeech tasks to test the physiologic integrity of the pulmonary, laryngeal, and velopharyngeal systems. The software features context-sensitive help, on-line transducer calibration, and near real-time results. For hard-to-test patients, a user-specified protocol allows collection, display, and a limited set of analysis functions for up to four channels of data. The expert system will assist interpretation of data obtained for a single protocol and also interrelate results among protocols. Recommendations will be made regarding efficient diagnostic sequence and need for additional data.

Methodology—Programs are written in the C language by a professional team of programmers. Algorithms are developed and tested. Studies of normal and speech-disordered subjects have assisted in testing reliability and validity of the protocols under development. A panel of experts are assisting in development of the expert system.

Future Plans—The programming effort will be directed at continued refinement and validation of protocols and development of the expert system. Phase I Beta-site software (exclusive of the expert

system functions) has been placed in four to five VA facilities, a private research institution, and a university training program. We expect feedback from these clinical and research users to contribute substantially toward continued enhancement of the system. Automated comparison with available normative data will be implemented for all protocols. The expert system will be refined through comparison of expert system recommendations with independent recommendations produced by the expert panel. Finally, additional normative data will be acquired through coordinated use of the system in cooperating facilities.

Recent Publications Resulting from This Research

- Computer-Assisted Evaluation of Speech Disorders: Rationale and Directions for Future Development. Till J, *J Comput Users Speech Hear* 6 (2):134-148, 1990.
- Listener Experience and Perception of Voice Quality. Kreiman J, Gerratt B, Precoda K, *J Speech Hear Res* 33:103-115, 1990.
- Aerodynamic and Temporal Measures of Continuous Speech in Dysarthric Speakers. Till J, Alp L, in *Dysarthria and Apraxia of Speech*, 77-93, C. Moore, K. Yorkston, D. Beukelman (Eds.). Baltimore: P. Brookes, 1991.
- Use and Perceived Value of Perceptual and Instrumental Measures in Dysarthria Management. Gerratt B, in *Dysarthria and Apraxia of Speech*, 77-93, C. Moore, K. Yorkston, D. Beukelman (Eds.). Baltimore: P. Brookes, 1991.
- Individual Differences in Perception of Voice Quality. Kreiman J, Gerratt B, Berke G, *J Speech Hear Res* (in press).
- Laryngeal Paralysis: Theoretical Considerations and Effects on Laryngeal Vibration. Smith M, Berke G, Gerratt B, *J Speech Hear Res* (in press).

[385] Development of Microcomputer and Clinician Treatment Procedures for Aphasia

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Sponsor: VA Rehabilitation Research and Development Service (Project #C343-2RA)

Purpose—The first objective of this investigation is to provide 21 aphasic adults of various severity levels an opportunity to achieve significant increases in their level of communicative functioning, using a well-established, reliable treatment procedure. The second objective is to establish the most effective linguistic cueing hierarchy for various types and levels of aphasia in two treatment mediums: microcomputer/clinician-assisted treatment, and

treatment by clinician alone. The third objective is to determine whether streamlining the treatment package can be efficacious to overall language recovery of aphasia by eliminating and/or rearranging treatment levels.

Preliminary Results—Data analyzed thus far has indicated that 15% more visits were required to reach criterion with the computer than with the

clinician. Of 21 patients analyzed, 6 experienced greater efficiency with the computer delivery system. Treatment effects were shown to generalize to within class response sets, and gains were demonstrated beyond chance (0.05) levels. A hierarchy of "wh" cues existed, with "who" being easier than "what" for subject-verb combinations. The hierarchy of "wh" cues was *who*, *what*, *when*, *where*, and *how* for subject-verb-object combinations. Fluent and nonfluent aphasic patients performed similarly. All gains achieved by the subjects were maintained at 1 month post-termination of the program. The computer program has been revised, and final revisions

based on patient responses will be accomplished in the near future.

Implications—The results of this study provide the clinician with a reliable, efficacious treatment methodology for delivering treatment to aphasic patients. The program provided addresses and meets the criterion outlined by the VA Advisory Committee on computer applications in speech and hearing. Final program revisions and dissemination will make this program available to clinicians treating aphasic subjects.

[386] Influence of Topic and Listener Familiarity on Aphasic Language: A Pilot Study

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Sponsor: VA Rehabilitation Research and Development Service (Pilot Project #C89-48PA)

Purpose—This pilot investigation was completed at the end of September 1991. The primary purpose of the study was to examine the influence of two situational variables on the verbal output of aphasic individuals: 1) the familiarity of the topic to be talked about; and, 2) the familiarity of the listener.

Methodology—Twenty-three adults with aphasia, categorized according to aphasia syndrome (Broca's, conduction, or anomic), served as subjects in this investigation. Ten normal speakers were also included as controls. Each subject was seen for two testing sessions. During the first session, tasks designed to determine syndrome of aphasia were completed (for aphasic subjects only), as well as story retelling (familiar and unfamiliar topics) with the familiar or unfamiliar listener and procedural discourse (familiar and unfamiliar topics) with the familiar or unfamiliar listener. Two weeks later, the second session was completed, with the tasks being story retelling and procedural discourse (familiar and unfamiliar topics) with the listener that was not included in the first session.

Upon completion of the second testing session, subjects completed a questionnaire pertaining to their personal familiarity with the specific topics classified by judges as familiar/unfamiliar for pur-

poses of this investigation. This measure was used to rule out any idiosyncratic differences in topic familiarity that may occur for a given subject. If a topic that had been classified by judges as familiar was rated as unfamiliar by a given subject, transcripts pertaining to that topic were not scored. Similarly, any topic rated as unfamiliar by a given subject that had previously been considered by judges as familiar was treated in the same manner.

Subjects' verbalizations were scored from written transcriptions of the tape-recorded testing sessions. There were 40 different story/procedural discourses to analyze for each subject (five familiar and five unfamiliar topics for the two tasks produced, once for a familiar and once for an unfamiliar listener). The basic unit for segmenting the transcribed discourse was the T-unit, which has been defined as one independent clause plus the dependent modifiers of that clause. Utterances were analyzed according to a number of measures of verbal complexity. Only utterances pertaining to the specified topic were scored; irrelevant utterances were not scored. The following is a list of verbal complexity measures completed: 1) mean length of utterance—the average number of words in an intelligible verbalization (this measure has been found to correlate well with parameters of verbal

complexity); 2) amount of embedding—expressed as the number of clauses per T-unit; 3) percentage of dependent clauses from total clauses; 4) percentage of nonfinite clauses from total clauses; and, 5) vocabulary size—a measure sensitive to language pathology.

Progress—Data input and statistical analyses are presently underway.

Implications—Results obtained in this investigation will have important implications for professionals involved in the diagnosis and treatment of aphasic patients. First, aphasia test batteries administered by clinicians (unfamiliar listeners) using standardized (unfamiliar) stimuli will likely elicit a language sample that is not representative of language produced in a more natural environment (familiar

listener/topic). Linguistic analysis of the verbal output produced by aphasic patients in the experimental conditions included in this investigation will indicate whether language complexity varies according to the familiarity of the topic and/or the listener. In addition, the specific linguistic features as well as the particular syndromes of aphasia influenced by these variables will be identified. Findings will indicate whether current standardized testing methods used with aphasic patients accurately reveal patients' linguistic capabilities. If they do not, findings will indicate specific ways in which they fall short and how they could be modified to more accurately define patients' speech/language abilities. Furthermore, results obtained in this investigation will be useful in treatment planning and implementation with aphasic patients.

[387] Characteristics of Tracheoesophageal Voice in Four Prosthetic/Occlusion Conditions

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Sponsor: *VA Rehabilitation Research and Development Service (Project #C499-RA)*

Purpose—This 3-year investigation was completed at the end of September 1991. The primary purpose of the study was to examine the impact of type of voice prosthesis and nature of tracheostomal occlusion on perceptual and acoustical characteristics of tracheoesophageal (TE) speech in males. The four prosthetic/occlusion combinations used by each tracheoesophageal speaker were as follows: 1) Blom-Singer duckbill prosthesis with digital occlusion of the tracheostoma; 2) Blom-Singer duckbill prosthesis with the Blom-Singer tracheostoma valve; 3) Blom-Singer low-pressure prosthesis with digital occlusion of the tracheostoma; and, 4) Blom-Singer low-pressure prosthesis with the Blom-Singer tracheostoma valve. Patient variables such as age, radiation therapy, radical neck dissection, myotomy, and whether the TE puncture was performed as a primary or a secondary surgical procedure were catalogued to allow for examination of the influence of these variables on perceptual and acoustical aspects of TE speech. Normal speakers were also included as subjects to serve as controls.

Methodology—The experimental protocol required that each subject be video- and audiotaped while performing a variety of speaking tasks. Each subject with laryngectomy performed these tasks four times, once using each of the prosthetic/occlusion combinations.

For the perceptual portion of the study, three judge groups, varying in their knowledge of laryngectomees, viewed the videotapes and rated the speaking proficiency of each normal subject and each laryngectomee using each of the prosthetic/occlusion combinations on the following parameters: voice quality, pitch, speaking rate, loudness, intelligibility, visual presentation during speech, extraneous speaking noise, and overall communicative effectiveness.

For the acoustical portion of the study, audiotapes were used to extract the following acoustical information for normal and laryngectomee subjects using each of the prosthetic/occlusion combinations: fundamental frequency (including mean, standard deviation, and range), mean, and

standard deviation, of jitter, jitter ratio, directional jitter, mean intensity, mean and standard deviation of shimmer, and directional shimmer. The following temporal factors were also measured from the audio recordings: number of words read per minute, total pause time, percentage of total reading time occupied by pauses, total phrase time, number of words per phrase, and mean maximum phonation time.

Progress—Data input and statistical analyses are presently underway.

Implications—Knowledge about how others per-

ceive/rate voice produced with various combinations of voice prostheses and stomal occlusion, as well as the extent to which acoustical characteristics of the resultant voice approximate laryngeal voice, will likely affect patients' choice regarding voice prosthesis and method of stomal occlusion. In addition, the research design and statistical analyses will identify voice characteristics of tracheoesophageal puncture patients that are the most aberrant (most different from laryngeal speakers). These are the characteristics that should be the focus of speech therapy with such patients.

[388] Augmentative Communication for Intensive Care Unit Patients

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Sponsor: VA Rehabilitation Research and Development Service (Project #C563-RA)

Purpose—The inability of Intensive Care Unit (ICU) intubated patients to communicate verbally has been identified as a major stressor. Communication aids may help to alleviate the stress of this hospital experience. Despite the availability of commercially produced augmentative communication devices, there is no one system that meets the immediate needs of the ICU patient. The major objective of this project was to determine whether the Intensive Care Communicator, a software program developed by Kevin Neelands (Acumen Software, 1986) for use with Apple and IBM hardware, was designed solely for use by ICU patients. The Intensive Care Communicator program could effectively be utilized as a means of communication among intubated patients, staff, and family members.

Progress—The pretest designed to assist in participant selection has been developed into a software program by Kevin Neelands to determine patient candidacy for the ICC. However, inasmuch as the ICC is easy to set up and operate, patients' general

cognitive functioning could be assessed via the ability to utilize the program. Need for the pretest, therefore, was found to be minimal.

Word lists for overall patient use have been finalized. An editing program allows customization of word lists to suit individual patients.

Data collection and final report have been completed. Both computers (i.e., hardware) and software programs are fully functional at present.

Results—A computer program was developed to assist with the communication needs of intubated patients in Intensive Care Units. The program was found to be successful in meeting the immediate needs of the ICU patient. The device is easily removable in times of emergencies, requires minimal movement and effort to operate, has an appropriate and useful vocabulary, has the capacity to store information for later use, can be easily viewed by the patient, and can be learned in a short period of time.

[389] Promoting Generalized Language Use: An Analysis of Treatment/Subject Variables

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Sponsor: VA Rehabilitation Research and Development Service (Project #C330-3RA)

Purpose—This research program consists of three studies designed to further our understanding of the principles and procedures that may explain and produce generalization of functional communication skills in aphasic adults.

Methodology—The descriptive portion of the program examines the effects of number of conversational partners, familiarity of conversational partners, sampling procedures, and sampling environment on the relative use of a variety of functional and structural parameters of language in the conversational discourse of aphasic and normal adults. This investigation will provide data relevant to contexts for assessment of communicative behaviors, leading to identification of conditions appropriate for stimulus generalization probing; identify areas of deficit in the conversational discourse of aphasic individuals and therefore provide data for selection of treatment targets; and, provide normative data for evaluating the social validity of treatment effects derived in the experimental portion of the program.

The experimental portion consists of a number of single-subject experimental investigations of the effects of a generalization training procedure on the subjects' use of targeted language behaviors (i.e., communicative functions and/or sentence structures) identified on the basis of subjects' performance in the descriptive study. A multiple baseline design across behaviors, subjects, and settings is being employed.

The final phase of this program will examine the relationship between outcome measures of generalization and subject variables, including severity of aphasia, severity of auditory comprehension deficit, and personality factors.

Progress/Preliminary Results—The conversational speech samples of 13 aphasic and 13 normal subjects

have been collected across 8 different sampling conditions (i.e., 208 conversational speech samples) and subjected to statistical analyses. Preliminary results reveal significant main effects of group, familiarity of conversational partner, number of conversational partners, and sampling procedures on a variety of structural and communicative function variables. Significant interaction effects were also observed indicating superior performance of aphasic subjects in topic-constrained, versus topic-open, sampling condition with familiar conversational partners.

Four subjects are currently receiving treatment designed to target six communicative function categories identified as being deficient in their conversational speech samples. Preliminary analyses reveal that subjects are acquiring and using targeted forms in unfamiliar dyad conditions, but that generalization programming may be necessary to transfer treatment effects to familiar dyad conditions.

Future Plans—We plan to refine treatment procedures and replicate treatment studies across targeted behaviors and subjects to establish the reliability and generality of the intervention.

Recent Publications Resulting from This Research

Conversational Discourse of Aphasic and Normal Adults: An Analysis of Communicative Functions. Wambaugh J et al., in *Clinical Aphasiology*, T. Prescott (Ed.), (in press).

Effects of Setting Variables on Aphasic and Normal Adults' Conversational Discourse. Doyle PJ, Thompson CK, presented at the Annual Convention of the American Speech Language and Hearing Association, Atlanta, GA, 1991.

Facilitating Functional Conversational Skills in Aphasia: An Experimental Analysis of a Generalization Training Procedure. Doyle PJ, Oleyar K, Goldstein H, in *Clinical Aphasiology*, Vol. 19, 229-241, T.E. Prescott (Ed.). Boston: Little, Brown & Company, 1991.

Stimulus Condition Effects on Linguistic Behavior in Aphasic Adults' Conversational Discourse. Thompson CK, Doyle PJ, presented at the Academy of Aphasia, Rome, Italy, 1991.

[390] Optimal Integration of Control Techniques Utilizing Speech Recognition: Computer-Aided Selection and Design of Computer Productivity Support for Individuals with Neuromotor Disabilities

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Sponsor: National Institute on Disability Research and Rehabilitation

Purpose—For individuals with neuromotor disabilities, speech recognition can serve as an additional method for interaction with a computer that can allow increased performance and productivity. Even if the speech production capabilities of the user are decreased, as is the case with dysarthric speakers, careful design of control vocabulary and input-output mappings can be used to exploit the capabilities of recognition systems. Similar selection and design can also be used to exploit other input devices when combined with an assessment of the residual motor abilities of the user. This project is investigating the issues involved in the design of vocabularies for dysarthric speakers to use with speech recognizers, in the context of a design scheme for computer interfaces that combine speech input with motor-based input devices. This design scheme will be based on objective assessment, user modeling, and performance prediction.

Progress—Speech samples from normal and dysarthric speakers have been collected in order to test the capabilities of the recognition system and the recognition accuracy of various potential control utterances. In order to provide the dysarthric speaker with a vocabulary that is both easily pronounced and reliably recognized, lists of potential control words are being developed. In addition, software is being developed to automate the collection and analysis of speech samples. This testing is currently underway.

Methodology—Speech samples collected from dysarthric individuals will be used to study the relationship between the size, recognition accuracy,

and phonological characteristics of selected vocabulary sets. These data will be used to develop heuristic and evaluation procedures for identifying optimal sets of utterances. The assessment of the dysarthric speech capabilities of an individual will be integrated into a comprehensive assessment of all potential control modalities, in order to form a model of the behavior of that person. This model will be used to predict performance with various interfaces, thus providing a metric that can be used to select and design an interface configuration (possibly consisting of several different modalities) that maximizes rate, user comfort, and ease of use.

Future Plans/Implications—In order to suit the needs of the individual user, the interface design system will eventually allow the user to configure his or her own system. By providing the individual with the tools necessary to adjust his/her working environment, an adaptable interface design system will offer the flexibility necessary to account for the evolving needs of the user.

Recent Publications Resulting from This Research

Evaluation of Computer Access Technology—Conceptual Extension of the Tufts-MIT Prescription Guide. Rosen M, Goodenough-Trepagnier C, in Proceedings of the 12th Annual Conference of the IEEE Engineering in Medicine and Biology Society, 1310-1312, 1990.

Towards a Method for Computer Interface Design Using Speech Recognition. Goodenough-Trepagnier, C, Rosen MJ, in Proceedings of the 14th Annual RESNA Conference, Kansas City, MO, 328-329, 1991.

Cognitive Constraint Rules in Design of Multi-Mode Computer Interfaces for Disabled Users. Rosen MJ, Goodenough-Trepagnier C, in Proceedings of the 13th Annual Conference of the IEEE Engineering in Medicine and Biology Society, Orlando, FL, 1991.

[391] Evaluation of the Functional Communicative Benefit of VIC for Persons with Chronic Global Aphasia

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Sponsor: National Institute on Disability and Rehabilitation Research

Purpose—VIC is a visual language technique for individuals with severe aphasia, developed at the Boston VA Medical Center and first implemented on a computer (as C-VIC) at the Palo Alto VA Medical Center. This study undertakes to evaluate the impact of VIC training on a number of aspects of aphasic VIC users' language and communicative function: 1) relative benefit, in terms of improvement in aphasic symptoms, of VIC versus natural language training; 2) relative communicative effectiveness of VIC-trained versus traditionally-trained patients; 3) characterization of VIC "competence" acquired compared to language competence regained by traditionally treated patients; 4) effect of alternative techniques on the patient's sense of well-being; 5) predictive value of patient characteristics for functional communication; 6) predictive value of patient characteristics for VIC acquisition; and, 7) characterization and comparison of VIC performance with natural language performance of VIC-trained patients.

Progress—Software written in C language for use on Macintosh computers emulates the VIC user interface and provides improved flexibility, lexicon capacity, and ease of customization. The revised program, NEWVIC, incorporates an automatic training progression for patients learning to use the system, a data acquisition component as an integral part of the automatic training progression, and optional monitoring of functional use of the system at home. Subjects are currently being enrolled in the NEWVIC study at Tufts and at the Rehabilitation Institute of Michigan.

A pilot C-VIC study of two patients with chronic severe expressive aphasia indicated that there are important differences among individuals within the population of severely aphasic patients, including differences among patients with similar relative sparing of comprehension, which affect the extent of benefit (e.g., VIC performance), as well as

the type of benefit—gains in functional communication, reading comprehension, and benefit to state of mind.

Three patients have received training on an early version of NEWVIC. One patient successfully completed the training available (in 14 sessions), including two locative prepositions, and intransitive and transitive sentences with and without indirect object, and will resume training with the additional levels since developed. The second acquired intransitive and transitive sentences (no indirect object), but then withdrew due to scheduling difficulties (after 10 sessions). The third did not maintain reliable performance beyond concrete noun selection (through 15 sessions). He will begin utilizing the system during a trial period at home to assess its functional value for him.

Three more patients have now been enrolled in the study, using the latest version of NEWVIC. Two are currently in the pretraining assessment phase. The third has already progressed to successful comprehension and production of sentences involving prepositions (e.g., "Jim put the pencil in the box"), and transitive sentences containing indirect objects (through 15 sessions).

Methodology—Subjects are adults with global or severe expressive aphasia (at least 6-months post-stroke) with unilateral lesions. Repeated assessments of aphasia prior to enrollment are carried out to assure a stable baseline. Patients are then randomly assigned to control (traditional therapy), and experimental groups (VIC) (at the Rehabilitation Institute of Michigan), or to an experimental group only (at Tufts). Pre- and post-measures are carried out to address the questions noted above.

Results—Preliminary results are consistent with the pilot study, indicating major differences among patients, not predictable from comprehension

scores, particularly with respect to success in representing relational meaning.

Future Plans/Implications—The study outcome will include guidelines for selecting patients for VIC training, for structuring the system and training, and for modifying the technology. It should also provide indications for new directions of research.

C. Vision Impairment

[392] Motorized and Autofocus Control Systems for Telescopic Low Vision Aids

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Sponsor: VA Rehabilitation Research and Development Service (Project #C557-DA)

Purpose—Many visually impaired individuals use miniature telescopes to provide magnification of near and distant objects. These devices are typically hand-held or mounted in spectacle frames, and focus is usually achieved by twisting the outer barrel. Unfortunately, users often encounter problems while using telescopes, many of which can be traced to the twisting nature of the focusing operation. The most frequent problems include loss of the target from the field of view, blurring due to jiggle, and reduced ability of persons with muscular problems, arthritis, or peripheral neuropathy to manipulate the device. A potential solution to many of these problems is to motorize the focusing process and make it a single-handed operation. The purpose of this project is to develop and test four telescope systems that incorporate two levels of motorized focus control.

Methodology—In the first level of motorized focus control, we will add a simple motorized focus control system (motor, drive train, power unit, and controls) to hand-held and spectacle-mounted telescopes. In the second level, we will use existing autofocusing camera technology and/or an autofocusing system we devise to construct autofocusing hand-held and spectacle-mounted telescopes. All prototypes will be evaluated in the laboratory and also in the field. Field testing will

Recent Publications Resulting from This Research

Functional Communication Using VIC. Goodenough-Trepagnier C, in Proceedings of the Annual International Conference of the IEEE Engineering in Medicine and Biology Society, 12(3):1313-1314, 1990.

A Knowledge-Based System for People with Aphasia. Goodenough-Trepagnier C, in Proceedings of the Annual International Conference of the IEEE Engineering in Medicine and Biology Society, 1991 (in press).

involve comparing performance of traditional hand-focus telescopes, motorized-focus telescopes, and the autofocusing telescope on target localization and identification tasks. Visually impaired individuals who are experienced hand-focus telescope users will serve as subjects. Also, we will examine the issue of training time versus performance with the traditional and prototype devices.

Progress—Five hand-held telescopes have been constructed. They include three motorized focus telescopes of 4, 6, and 8X magnification power and two autofocusing telescopes with variable magnification (2.5 to 5X and 6 to 10X). Motorization of focus of the first three telescopes was achieved by adding miniature motors, geared drive trains to effect telescope barrel movement (mechanism of focus), batteries, and a two pushbutton control system to off-the-shelf Keplerian-type hand-focus (manual) telescopes. The two autofocusing systems are modified autofocusing camera lenses. Field testing of these hand-held devices is currently underway, with no data analyzed. In addition, two spectacle-mounted motorized focus telescopes have been constructed. Field testing of these systems will begin when appropriate subjects have been identified. Finally, development work has begun on an auto-ranging system that will be added to the spectacle-

mounted devices to convert them to autofocusing systems.

Recent Publications Resulting from This Research

A Pilot Study of a Telescopic Low Vision Aid with Motorized Focus. Kuyk T, James J, *J Vision Rehabil* 4(4):21-29, 1990.

[393] Relationship of Auditory Skills to the Mobility of Blind and Visually Impaired Individuals

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Sponsor: *VA Rehabilitation Research and Development Service (Project #C438-RA)*

Purpose—Audition is the major sensory modality available to the blind for detecting aspects of the environment beyond the reach of the long cane or limbs. Auditory training is widely recognized as a major part of mobility training for persons with low vision and blindness. Mobility training curricula typically include specific practice on auditory skills that have high face validity (i.e., auditory skills that common sense suggests should be important for mobility). Examples of such skills include sound identification, sound localization in direction and distance, use of reflected sound for object/obstacle recognition, echo detection to identify openings, and sound shadow recognition.

However, there is now little scientific evidence concerning how and to what extent auditory skills contribute to the mobility capabilities of persons with low vision and blindness. For example, it would be valuable to know which auditory skills are most useful in mobility, how the contribution of auditory skills to mobility is related to the extent of visual impairment, and whether there are important individual differences in the extent to which persons with visual impairment use auditory skills in mobility.

The primary goal of this project is to determine how and to what extent auditory skills contribute to the mobility of persons with low vision and blindness. A secondary goal is to determine how the contribution of audition to mobility differs for special populations who have a visual impairment and are elderly, hard of hearing, or are users of hearing aids.

Progress—The testing equipment is currently at the VA Medical Center Blind Rehabilitation Center in Birmingham, AL. Modifications in the testing protocol have been implemented, and approximately 20

subjects have completed testing. An additional 24 subjects have had the pretest and are in training. The control group is currently being tested. Other subjects have been evaluated but have not met the selection criteria.

Methodology—The proposed research will examine the role of auditory skills in orientation and mobility of persons with visual impairment. Mobility performance of the visually impaired depends on many factors: sensory, cognitive, motor, motivational, social, historical, and situational. Therefore, a cross-sectional correlational study would be expected to yield only a low or moderate correlation between proficiency at any given auditory skill and mobility performance. The present research will therefore relate changes in auditory skills within individuals, because of training, to concomitant changes in mobility performance. This approach reduces the extent to which other factors can obscure the relationship between auditory skills and mobility, since there is likely to be much less variability in potentially confounding factors within subjects than between subjects.

The relationship of auditory skills to mobility performance will be evaluated for six groups of subjects who differ on extent of visual impairment, age, hearing ability, and use of a hearing aid. Performance on 10 auditory skills will be measured before and after mobility training for half of each group assigned to a treatment condition, or before and after a comparable waiting period for the remaining half assigned to a control condition. Multivariate analysis of variance (MANOVA) and multiple, step-wise correlation will be used to determine how and to what extent auditory skills are related to mobility performance.

[394] Design and Testing of an Electronic Travel Aid for Blind Persons

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Sponsor: VA Rehabilitation Research and Development Service (Project #C637-RA)

Purpose—The main purpose of this 3-year project is to update and improve the electronic and mechanical design of an electronic travel aid (ETA) called the Laser Cane. A second purpose is to investigate the degree to which people with a visual impairment using a Laser Cane benefit from the improved mobility provided by the device during independent travel.

Specifically, improvements will be made in the Laser Cane's electronics design, including the use of plug-in integrated circuits to reduce maintenance costs, improve reliability, and provide a more dependable power supply. The new device also will use standard batteries instead of the custom-designed battery presently required. Improvements in mechanical design will include reduction of the diameter of the cane and relocation of the vibrotactile outputs to better fit people with small hands. The cane will be made substantially lighter than the present model, and will be redesigned to make it collapsible. These improvements in engineering design will be made in the first phase of the project. The primary benefit of these improvements will be a reduction in cost to the visually impaired consumer over the existing model. This new product should be within financial reach of many more visually impaired consumers.

Progress—The contract to redesign the Laser Cane

was awarded to Nurion Industries, Inc., located in Paoli, PA. A prototype has been designed. A product prototype and working test models are expected to be finished by early 1992.

Methodology—This study consists of two parts. Part 1 is the proposed engineering redesign involving the following activities: 1) electrical redesign; 2) optical redesign; and, 3) mechanical redesign.

An evaluation of Laser Cane use in natural environments will be conducted during the second phase of the project. Two groups of individuals will participate in the evaluation. The first group will be made up of former and present Laser Cane users living in the metropolitan areas of Philadelphia and Chicago. The travel ability of individuals using the newly designed Laser Cane (ND-8) will be assessed using an established methodology for mobility assessment. Participants also will be evaluated while traveling with a standard long cane.

The second group will be made up of students in training to become mobility specialists. They will receive training on the new electronic travel aid, and their mobility performance (blindfolded) with and without the ETA will be assessed. Travelers in both groups will provide subjective evaluations about design features and will provide ratings of general usefulness of the two models.

[395] Environmental Information Needs for Wayfinding by Special Populations

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Sponsor: VA Rehabilitation Research and Development Service (Project #E561-RA)

Purpose—Independent travel is a hallmark of effective functioning in everyday situations. Although the skills involved in traveling to and from destinations

are taken for granted by a large portion of the populace, the development of these skills represents a critical challenge for mobility-impaired individu-

als. To a significant extent, the acquisition and successful application of mobility skills depends upon access to environmental information.

Research is needed to determine the form and content of requests for wayfinding information that are most appropriate for a given environment and for a given population. Assessment of information needs of a variety of populations of people will lead directly to the development of a data-based scheme for accessing such information. This assessment is intended to be incorporated into an automated interactive system to assist a variety of travelers, including individuals with visual impairment, older adults, and individuals with various disabling conditions.

Progress—At present, routes have been developed. The indoor route is in the Atlanta VA Medical Center and there are two outdoor routes, one in a residential section of Decatur, GA and another on the campus of Agnes Scott College (also in Decatur). Pilot work is completed on all the routes as are scoring techniques, permission forms, and protocol. Subjects are currently being tested. Assessment of elderly adults has been completed, and wheelchair and subjects with visually impairment are being tested presently.

Methodology—*Phase 1: Development of Environmental Information Base(s)*. This phase involves the collection and organization of data concerned with the environmental information needs of 6 groups of 14 participants each. Data collection will take place during two wayfinding exercises, one outdoor exercise and one indoor exercise. The six groups are as

follows: 1) legally blind (20/200 acuity to light perception) adults aged 25 to 60 years; 2) totally blind (no light perception) adults aged 25 to 60 years; 3) partially sighted (20/70 to 20/200 acuity) adults aged 25 to 60 years; 4) normally sighted adults confined to a wheelchair and aged 25 to 60 years; 5) adults aged 65 to 80 years who are not visually or mobility impaired; and, 6) a control group of adults aged 25 to 60 years who are not visually or mobility impaired.

Participants are taken to the beginning of the route and instructed to ask questions that give them information on how to get to the end by way of a prescribed route. They must ask specific questions that will reveal the type of information needed and the amount needed at various points along the walk. As the participant walks along the route, the experimenter records the participant's path of movement on a map of the area. Following the trip, participants provide a complete and accurate description of how to get from the beginning to the end of the route. An audiovisual recording of participants' verbal and locomotor behavior is made on the trips and during the direction-giving procedure at the completion of the trip.

Phase 2: Assessment of Environmental Information Base(s) as Wayfinding Aids. This phase of the project will determine the usefulness of the hierarchically organized environmental information schemes constructed in Phase 1. In the context of a wayfinding exercise, participants' need for information will be addressed exclusively by an experimenter using the hierarchical scheme in menu format. In summary, participants will be able to access specific categorized information only.

[396] Spatial Orientation and Wayfinding in Elderly Persons

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Sponsor: VA Rehabilitation Research and Development Service (Project #E-428RA)

Purpose—A major problem for many elderly persons is that of becoming lost or disoriented when attempting to move about familiar as well as unfamiliar environments while engaged in everyday life activities. In a past survey of 170 nursing homes, it was found that such disorientation characterizes a

significant portion of the nursing home population.

The component processes of wayfinding, particularly among older individuals, are poorly understood. To provide a better understanding of the wayfinding abilities of older persons, this 3-year study examined: 1) the ability of older people to find

their way around new and unfamiliar places; 2) changes in wayfinding abilities as people age; and, 3) variances in abilities of older and younger people to find their way around new and unfamiliar places.

Individuals of two specific age groups are to be compared in an unfamiliar institutional setting. The comparison included the efficiency of wayfinding, which involves the components of: 1) knowledge of the environment; 2) knowledge of one's location in relation to specific landmarks in the environment; and, 3) retrieval and usage of this information. Factors related to wayfinding competence in the elderly population were studied in the residential setting, and included: 1) frequency and range of travel; 2) wandering behavior; and, 3) memory.

Progress—Thirty-four middle-aged volunteers have been identified and tested in a unfamiliar environment at the VA Medical Center (VAMC), Decatur, GA. Twenty older adults are involved in the study, some having completed the testing at the unfamiliar VAMC environment. Most of these participants are completing the longitudinal portion of the study.

Methodology—This study has two parts. Part 1 is a comparison of measures of spatial ability in an unfamiliar building following a brief, controlled exposure to the building. Thirty-four middle-aged (18–50 years) and 34 older adults (65 and up) participated in the study. One objective of the project is to compare the performance of these older adults on this controlled task with spatial behavior in a more natural setting (i.e., the independent living center). Therefore, the elderly adults selected for

participation are individuals recently admitted to a large retirement center. Part 2 was a follow-up of the older adults after their admission to the retirement center. It was designed to examine the relationship between wayfinding competence, as measured in Part 1, and various measures of adjustment to the nursing home. The subjects' general level of functioning was to be assessed in these areas: spatial orientation and wayfinding competence in the nursing home and immediate environment, self-confidence in wayfinding, range of travel, wandering behavior, and memory. These assessments took place at 2 weeks after admission, 2 months, 6 months, and each 6-month interval thereafter for a period of 2 years.

Older adults selected for participation were individuals who had recently (within 2 weeks) moved into a large retirement center. Middle-aged adults were selected among recently hired employees or volunteers of the Atlanta VAMC, Decatur, GA.

Preliminary Results/Implications—Data are being collected on 20 older subjects. These data and that of the 34 middle-aged subjects are currently being analyzed, and we are continuing to collect longitudinal data. The results of this study will have implications for understanding the effects of the aging process on spatial orientation and wayfinding. In addition, this study will have applied implications for orienting older adults to new environments. Depression and problems adjusting to new settings may be reduced as a result of applying the knowledge gained in this study.

[397] Development and Validation of Criteria for Task Safety in Blind Mobility

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Sponsor: VA Rehabilitation Research and Development Service (Project #C585-RA)

Purpose—Early in the history of the field of orientation and mobility (O&M), most clients were young, relatively healthy, and "simply" visually impaired. Today, many veterans are older and many have multiple impairments. Because of these changes, evaluation of the ability of the client to

safely perform a specific O&M task has become much more complex.

In the fall of 1988, a conference of experts in the field of O&M experienced with multiply handicapped individuals was convened at the Atlanta Rehab R&D Center. This meeting generated a

complex matrix of O&M tasks, environments, skills, and functional prerequisites (sensory, motor, and cognitive). While this matrix cannot be validated experimentally, this project seeks to refine and validate it as a representation of "best professional judgment."

For example, clinicians must take into account the degree of remaining vision of an individual, other sensory abilities, cognitive and physical status, and personality variables. The O&M specialists are required to make decisions concerning the capabilities of the client on a continuous basis without any recourse to a standardized body of professional knowledge. Prior to the Hill and Ponder (1976) and the Welch and Blasch (1980) text books, all O&M knowledge was exclusively in the heads of the "experts." Now O&M professionals have general information but find themselves lacking specific information regarding which competencies are required for a given client in a given situation in order to achieve a reasonable degree of safety.

Methodology—This task will be accomplished in three phases. The first phase will be the incorporation of the matrix into a knowledge-based, expert system. This system will be designed to determine if an individual with specified training and specified sensory, motor, and cognitive function can accomplish specified O&M tasks. The system will predict that within specified environments the visually impaired individual can perform with an acceptable level of safety. Once a prototype system is developed and demonstrates reliable and valid performance, the system will be used as a tool to achieve criterion consensus with a much larger panel of experts.

Areas of disagreement will be targeted for expansion and/or refinement of the knowledge base in this second phase of the project. In the third and final phase of the project, the final system will be subjected to reliability and validity testing. During this period it will be evaluated in university O&M instructor training programs, where it will be used as an adjunct to practicum experience by students. It will also be tested in VA blind rehabilitation programs, where it will be evaluated as a clinical decision-making tool. Between these two settings, we anticipate literally thousands of configurations of tasks and users to be tested and evaluated. A database of functional limitations causing negative decisions with no available options (either device or training) will be maintained in order to identify areas for future research.

Progress—The first year of the project objectives have been met. These include: 1) the development of a prototype expert system based on a matrix of O&M tasks, environmental characteristics, client skills, and client functional abilities; 2) the pilot testing of the prototype expert system; and, 3) initial evaluation of reliability and validity of the prototype expert system, manuals, and case studies.

Future Plans—Plans for the second and third year of the project include distributing the prototype system to all of the participating rehabilitation and university settings, convening a national meeting of experts to evaluate and refine the system, distributing and evaluating the revised system, and disseminating the results.

[398] A Pilot Study to Develop an Electroluminescent Aid for Low Vision Readers

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Sponsor: *VA Rehabilitation Research and Development Service (Project #B91-255AP)*

Purpose—This pilot project proposes to design, develop, and test a lightweight, portable, cool, glare-free lighting device for readers who are visually impaired. Many visual impairments require the

use of above-average lighting levels for visual task performance. Because low vision readers use high-powered magnification devices such as spectacle-mounted magnifiers, these impaired readers fre-

quently must use additional lighting close to the page of print. With the proposed reading aid, lighting will be provided via electroluminescent (EL) panels, which are used commonly in backlit screens for computer monitors. Initial experimentation has shown EL lighting may be very advantageous to persons who must use high magnification ($8\times$ to $20\times$) when reading. The advantages of EL lighting over conventional lighting (incandescent, fluorescent) are that EL lights have an extremely thin profile, remain cool to the touch, provide even lighting, are portable, and produce almost no infrared or ultraviolet radiation.

Progress—A prototype EL unit adapted with a 9-volt battery and a +20 diopter lens has been constructed, which has been useful for demonstration purposes. The prototype has been shown to several visually impaired individuals for feedback. Responses have been very favorable. They specifically mentioned the increase in lighting over room light alone, the heightened contrast from EL lighting on print or reading material, and the greater contrast for writing tasks when the form or page was backlit by the EL panel.

[399] Development of a Video for Instructing Family Members in Making Visual Environmental Modifications

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Sponsor: VA Rehabilitation Research and Development Service (Project #C512-RA)

Purpose—A videotape titled "A Vision of Independence," was developed as a part of a curriculum for instructing family members of veterans with low vision. Family members of veterans with low vision who attend the Blind Rehabilitation Centers (BRCs) of the Department of Veterans Affairs are invited to attend a 2-5 day support program. This program is designed to assist family members in understanding the veteran's visual impairment, and to train them in helping the veteran appropriately adjust to low vision. The purpose of the curriculum is to develop observable, measurable competencies for the low vision family training program, to assist the Visual Skills Section staff of the BRCs in developing

Methodology—The methodology of the pilot study will be separated into two phases: 1) design; and, 2) evaluation.

The first phase encompasses the design and development of the EL devices. Three configurations have been planned. The first design is a disk, 4 inches in diameter, with a 1-inch hole in it. This lamp could be attached to the frames of high-power spectacles. The second design is an arc, which could be wrapped into a cone shape, or "frustum," and inserted into a stand magnifier. The third design is a flat, rectangular sheet, approximately 8 1/2 inches by 5 1/2 inches, that would be attached to a clipboard and used to backlight forms.

The second phase is the evaluation of the EL devices. The developed device will be evaluated according to the following design criteria: The device 1) will provide amounts of incident light for close working distances similar to that provided by incandescent and fluorescent light sources; 2) must provide light without significant glare; 3) must remain cool to the touch, even after extended use; 4) must not require any additional lighting; 5) must increase contrast on the printed page; and, 6) must be inexpensive to produce (under \$20).

training tools and techniques, and to evaluate the low vision family training program. As a part of the curriculum, project staff were interested in assisting family members to adapt the home environment to make using limited vision easier and safer for veterans with low vision. However, staff of the Visual Skills Section of the VA's BRCs often do not have additional time to cover this subject with family members who attend the family training program. Therefore, the videotape was developed as a training tool to motivate family members to modify the home environment. These techniques assist the veterans in using their limited vision for greater independence.

Methodology—Behavioral objectives for the videotape were developed. Following the viewing of the videotape, the family member would be able to 1) suggest ways in which color, contrast, and lighting can be used to maximize the veteran's visual functioning at home and, 2) suggest some manipulation in the organization of space and the placement of objects that could enhance the visual functioning of the veteran at home. A video script was written and submitted to the Fry Index of Readability to assure that the script would be understood easily. The videotape was shot, edited, and finalized. The videotape is structured to impart helpful information while entertaining the audience. Simulations of visual impairment and techniques for increasing independence are described by a narrator and illustrated by a married couple performing daily activities in their home. Between the instructional segments, an elderly woman with a progressive visual impairment provides humor and elicits empathy. She tells the story of how visual impairment has affected her life. She also tells how she and her husband have adapted their home and lives to her impairment. Her anecdotes allow the audience to

identify with her character. An accompanying pamphlet, entitled "Environmental Modifications in the Home," was prepared to supplement the video. It is given to the family members as a written reminder of what they saw on the videotape. The pamphlet was also submitted to the Fry Index of Readability to assure that it was understandable to anyone with at least a fifth grade reading level.

Progress—The videotape is being distributed by the Atlanta Education and Research Foundation. International orders for the videotape have been received, and the videotape is being used as a training tool within the participating Blind Rehabilitation Centers, rehabilitation agencies, schools and colleges, and schools for the blind.

Implications—Videotape instruction has been used increasingly to educate a variety of audiences. The widespread interest in the videotape indicates that a need exists for this type of educational tool for family members who wish to modify the home environment for visually impaired persons.

[400] Development of an Objective Measure of Orientation Skill in the Blind: A Pilot Study

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Sponsor: VA Rehabilitation Research and Development Service (Pilot Project #C995-PA)

Purpose—We had two principal objectives for this study: 1) to analyze and describe the components of orientation skill in the blind; and, 2) to begin the process by which a short and easily administered test to assess orientation skill in blind persons could be constructed. The test is designed to be used by orientation and mobility instructors, as well as by researchers to study and learn more about orientation ability in the blind.

Methodology—The first phase of this study involved exploring and refining definitions of orientation, translating these into orientation assessment tasks, and pretesting those tasks with blind subjects. In phase two, we conducted a formal experimental test of the orientation tasks to determine their useful-

ness, reliability, and internal factor structure. In the third phase, we demonstrated that orientation and mobility instructors can use this orientation test.

Progress—The first objective has been completely met; we are presently preparing a monograph for publication in which the components of orientation ability are described in theoretical terms and then analyzed in terms of the research and clinical literature on orientation. The second objective also was met by three experiments we completed: one that analyzed a variety of measures of indicating orientation, and two multidimensional experiments that assessed 12 different components of orientation on samples of blind subjects. The first of these has been submitted for publication, and the latter two

are being prepared now for publication as a single report. From the results of these three experiments, we can now begin the preparation of the orientation test, one that can meet stringent psychometric standards.

Future Plans—The results of the component analysis of orientation and those of the three experiments all are important for researchers and clinicians

concerned with orientation in the blind. We summarized some of these in a conference presentation. These contributions to the literature now make it possible to proceed with the full development of a test. We plan to submit a regular proposal to the VA Rehabilitation Research and Development Service, in which we will propose the procedures to complete the work on this test of orientation ability.

[401] Low Vision Enhancement System (LVES) Development: Phase II

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Sponsor: VA Rehabilitation Research and Development Service (Project #C638-DA)

Purpose—The purpose of this project is to develop and test a high-technology low vision enhancement system (LVES). The specific goals are to: 1) develop and test a wide-angle, battery-powered, binocular head-mounted video display system (HMD); 2) develop and test a head-mounted video camera for the HMD that has zoom magnification, auto-focus, and image motion compensation features; 3) develop and test methods of measuring contrast enhancement, spatial filtering, and image remapping requirements of low vision patients; and, 4) develop and test vision-enhancing image processing algorithms that ultimately would be implemented on the LVES.

Progress—1) *HMD Development*: A stand-mounted prototype of the HMD has been built, and reading performance tests have been conducted on 40 low vision subjects. Focus interviews for designing the HMD frame have been conducted with 40 low vision subjects. HMD design models have been built. 2) *Video Acquisition System*: A prototype fiber imaging system, consisting of a high resolution 1/8 inch coherent optical fiber bundle and an image coupler to a CCD detector, has been developed to relay an image from the HMD frame to a video camera to be carried in a belt pack. 3) *Methods of Measuring Vision Enhancement Requirements of Low Vision Patients*: To determine spatial filtering requirements, we have developed a new test of spatial contrast sensitivity using a circular pattern (bull's eye). We expect this test to predict visibility of

objects better than conventional sine wave gratings. Preliminary testing has been completed on 24 low vision subjects. To determine contrast enhancement requirements, we have completed development of a contrast discrimination test (employing the above-described circular pattern). Preliminary testing has been performed on 19 low vision subjects. To determine image remapping requirements, we have completed development of a method for precisely mapping central and paracentral scotomas and mapping the retinal locus of fixation using the scanning laser ophthalmoscope. Preliminary data have been collected on 25 low vision subjects. We also have completed development and preliminary testing of a procedure for mapping perceived spatial distortions. Additional work to improve image stabilization for this test is in progress. To meet performance testing requirements, we have developed a method of measuring visual control of posture, and preliminary testing has been completed on seven low vision subjects. 4) *Development and Testing of Vision Enhancement Algorithms*: An algorithm for real-time image remapping has been developed and tested on static images. Preliminary to the development of spatial filtering algorithms, we have tested four low vision subjects to determine their ability to discriminate normal images of faces from images that have been filtered to remove spatial frequencies to which they are minimally sensitive. The preliminary data indicate that all spatial frequencies above the cut-off measured with our contrast sensitivity test can be filtered from the

image prior to enhancement. Preliminary studies of binocular contrast sensitivity indicate that mismatches of contrast or contrast sensitivity between eyes can lead to binocular suppression of contrast sensitivity in the better eye; this might be prevented with different contrast operations on the image to each eye.

Methodology—All vision tests employ standard psychophysical procedures. Postural adjustments are measured with a force platform. The scanning laser ophthalmoscope is employed to compare visual function with retinal features. Eye tracking for image stabilization employed a dual Purkinje image eye tracker for preliminary studies and now employs a scleral search coil system.

Results—Reading speed with the HMD is 50% of maximum achievable reading speed. Contrast, the relation of head to eye movements, vignetting of the exit pupil of the optical system by extreme eye movements, and pupil alignment stability are now being explored as possible limits to reading speed with the HMD.

Recent Publications Resulting from This Research

Battery Powered Head-Mounted Binocular Video Magnifier for the Visually Impaired. Massof R et al., in *Ophthalmic and Visual Optics Technical Digest*, Vol. 2, 64-66. Washington, DC: Optical Society of America, 1991.

Obstacles Encountered in the Development of the Low Vision Enhancement System. Massof RW, Rickman RL, *Optom Vis Sci* (in press).

[402] Development and Evaluation of a Videotape to Teach Staff of Long-Term Care Facilities About Residents' Vision Loss

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Sponsor: VA Rehabilitation Research and Development Unit (Core Funds)

Purpose—The purpose of this study was to develop and test videotape as a medium for delivering training to long-term care facility personnel. This video is to train staff in nursing homes about caring for their residents with low vision. Traditional long-term care staff development materials contain minimal information on the care of residents with low vision. Videotape saves money, resources, and time, and allows viewers to adjust the lesson to time available. It presents information in a consistent manner and has shown to be a useful medium for disseminating information. This study explored two types of videotape presentations for training long-term care staff on caring for residents with impaired vision.

Progress—A videotape was developed titled "Caring for Nursing Home Residents with Impaired Vision." The videotape was developed using goals and objectives to organize effective instruction. The objectives for the target audience were to: 1) recall the three major types of vision loss; 2) interpret residents' behaviors that signal changes in their visual status; 3) recognize the functional implications of vision

loss; 4) identify environmental factors that may affect visual functioning; and, 5) demonstrate sighted guide techniques.

Methodology—A pre- and post-test methodology was designed to test two different versions of the training video. One version of the videotape presented information entirely in a narrative format, while the second videotape version used text overlay to highlight key ideas. The action in the two videotape versions were identical. Subjects were 87 staff members of 3 different long-term care facilities. A pretest was administered to evaluate the nursing home staff's knowledge of the concepts presented in the videotape. The staff members were randomly assigned to view one of the two tape versions. After viewing the video, they took a post-test immediately; another post-test was administered 2 weeks later. Scores were obtained from the pretest and two post-tests. Subjects were asked to comment on the clarity of the information and its relevance to their job responsibilities. They were also asked to suggest ways to improve the instruction.

Results—A two-way analysis of variance (ANOVA) was used to analyze the results of the pretest and post-tests. Although there was no significant difference in the viewers' test results for the two versions of the videotape ($F=2.6$, $df=1/52$, $p<0.1$), there was a significant increase in total performance on the pre- and post-tests ($t=7.5$, $p>0.01$). The mean of the correct responses on the three 16-item tests are as follows: pretest, 10.1 (SD 2.6); immediate post-test, 12.2 (SD 2.8); 2-week post-test, 12.8 (SD 1.9). Significant differences were found between the three tests using ANOVA ($F=54.3$, $df=2/104$, $p>0.001$). The Tukey HSD method of multiple comparisons showed a significant difference at all levels of tests ($p=0.01$ level).

Implications—Videotape instruction proved to be an effective way to teach long-term care staff about caregiving for residents with low vision. The favorable comments and the significant change in scores

on the pre- and post-tests substantiated the value of videotape instruction. The staff members became better informed about signs of vision loss. They were more knowledgeable about useful skills and techniques that increase independence of visually impaired residents. They also had a better understanding of the problems created by vision loss. Videotape can be considered an effective and efficient tool for instructing personnel about vision loss in long-term care settings. The videotape won a second place in the training and education division of the 1990 OWL award, a national media competition sponsored by the Retirement Research Foundation.

Recent Publications Resulting from This Research

Videotape Simulations to Teach Staff of Long-Term Care Facilities about Residents' Vision Loss. Griffin-Shirley N, McNeely EA, Karwisch AH, J Visual Impairm Blindn 84(10):530-531, 1990.

[403] Marketing Media Prototype for State Business Enterprise Programs to Enhance Property Manager Presentations

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Sponsor: U.S. Department of Education

Purpose—The purpose of the Phase One grant was to conduct a feasibility study on the development of a marketing prototype that would enhance presentations of the Randolph-Sheppard (RS) vending program by state licensing agency (SLA) personnel to building managers, and thereby build market share for the Randolph-Sheppard vendors and greater participation in the Randolph-Sheppard Program by blind vendors.

Progress—The feasibility project identified and researched potential market alternatives for the Randolph-Sheppard Program. GSA provided numerical data on federal properties and this information was compared to the RS annual reports to determine the program's penetration level in the priority (federal) market. Models of successful market penetration (provided by SLA interviews) were evaluated as possible models for replication. Obstacles were identified.

Methodology—Primary research was conducted through interviews with vendors, state licensing agencies, property managers, key federal agency personnel and officers of organizations for the blind. Secondary research was conducted through materials gathered from advocacy groups for the blind and from research and training organizations that participate in Randolph-Sheppard. Research centered on the information needs and media design requirements of a marketing prototype presentation package, market expansion possibilities, successful model programs, technology for blind vendors, SLA capabilities, and levels of participation by qualified blind personnel.

Results—The two bodies of research were evaluated and three major conclusions were reached: the obstacles to a formal marketing effort are known. There is a need for a national marketing prototype for the Randolph-Sheppard Program. It is feasible

to produce. The research further indicated that the development of a marketing resource must begin with an understanding of the difference between selling and marketing. The majority of SLAs interviewed had little understanding of these differences and lacked the available personnel to comprehensively approach the market available to them. Simply looking at the presentation aspects of a marketing prototype will not produce the desired growth of the program. Growth will depend on the ability of Randolph-Sheppard vendors to serve well and compete with the private market. Research results indicated that available computer technology and information systems, supported with professional marketing resources, provide the necessary elements for future growth.

Future Plans—A test version of the marketing resource is now being developed. It is designed to help the SLA to identify and classify its markets, aid in the planning for additional business modules, provide market research and develop systems for decision support. In addition, the market resource would be tasked with the responsibility of analyzing

existing vending operations, with a view toward maximizing productivity. The comprehensive market analysis would provide a starting baseline for SLA expansion. This centralized prototype marketing resource would operate as an extension of the SLA work force, without the overhead costs normally associated with adding personnel.

Implications—Expanding the scope of the Randolph-Sheppard Program would benefit the multiple stakeholders. To the vendor, it means expanded opportunities for entrepreneurial experience without initial financial investment, equipment purchase, repair or replacement, and a guaranteed minimum income. To the property manager, it increases services to building occupants and visitors with minimum financial investment, offers a formal line of communications regarding the operation, shared responsibility of facility repairs, assurance of compliance with safety and health standards and a guarantee of a secure, stable operation. To the customer, it expands access to quality services and products at the lowest possible cost.

[404] Access to Graphics-Based Operating Systems for Blind Individuals: "Systems 3" Model

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Sponsor: *National Institute on Disability and Rehabilitation Research; Apple Computer, Inc.*

Purpose—Graphics-based operating systems pose severe obstacles to computer users with blindness and certain other visual impairments. Such systems require the user to visually recognize and locate words, boxes, on-screen buttons, and icons. Pointing to these images (usually with a pointing-based input device like a mouse) instructs the system to carry out commands. Users unable to visually orient themselves are thus unable to operate the system.

An important challenge in allowing transparent access to such systems for blind users is to provide a structured interface for presentation of the screen information so that blind users can interact with the computer in an effective and timely way.

Progress—A prototype special auditory-tactile computer access system has been developed and is being refined. A set of software development tools for such systems is also being created.

Methodology—The challenge of structuring the user interface is being studied in terms of a "Systems 3" model. This model allows for three different approaches to screen access, which could coexist in eventual commercial implementations.

In System 1, no additional special hardware component is used for navigating the screen. All commands and requests for information are issued using the keyboard. In System 2, a touch tablet is

used. The user can touch on "speed lists"—areas of the tablet that correspond to menus and messages—in order to specify what information is to be read back. In System 3, a "virtual tactile tablet" is added to the system. This tactile tablet allows the user to "feel" the image on the screen by using a mouse-like puck that contains a tactile array (similar to an Optacon).

Results/Future Plans—An initial prototype of Systems 3 has been developed. Four copies of the prototype have been created and are being used in field testing and experiments. Initial field tests have been successful. We are currently in the process of restructuring the system to allow it to function in a more modular way. We are working to convert the

basic access routines into a set of individual software tools. The goal is to develop versions of the tools for IBM and Macintosh computers, and then make sets of tools ("toolboxes") available to other vendors. This would allow the Systems 3 model to be exploited by any company interested in entering the market, helping to create the market diversity that currently exists for screen-access systems for older, character-based computers.

Recent Publications Resulting from This Research

Graphical User Interface: Crisis, Danger and Opportunity. Boyd LH, Boyd WL, Vanderheiden GC, *J Visual Impairm Blindn* 84(10):496-502, 1990.

Graphic User Interfaces: A Tough Problem with a Net Gain for Users Who are Blind. Vanderheiden GC, *Technol Disabil* 1(1):93-99, 1990.

[405] Tactile Perception and Business Graphics Studies

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Sponsor: National Institute on Disability and Rehabilitation Research

Purpose—A critical component in providing access to computers for individuals who are blind is the ability of the blind computer user to deal with information that cannot be easily interpreted and presented in words. The need for a nonvisual mode for presenting graphic information has led to the inclusion of a vibrotactile array in the prototype Systems 3 auditory-tactile computer access device developed at the Trace Center.

The vibrotactile array of the Systems 3 device allows individuals who are blind to feel shapes of graphics appearing on the computer screen. There are several aspects of this type of tactile presentation that can be varied, however, and the effects of these variations in optimizing the user's ability to derive information are not known. The purpose of this study is to examine different tactile presentation modes and compare their relative efficacy.

Progress/Methodology—A series of studies have been completed analyzing variables in tactile image perception. The studies looked at three variables in vibrotactile perception. Both sighted subjects (blind-folded) and blind subjects were tested. Subjects were

timed in their identification of tactemes (basic shape elements) and shapes (combinations of tactemes). The vibrotactile array was mounted in a hand-held puck, as in the Systems 3 device. Experiments used a $2 \times 2 \times 2$ design comparing: 1) same-hand versus cross-hand perception (i.e., whether the vibrotactile information was presented on the same hand with which the user moved the puck around the shape or on the other hand); 2) large versus small stimulus size (i.e., the absolute size as it appears on the computer screen of the image being perceived); 3) high versus low mapping ratio (i.e., the ratio of the number of pixels on the screen to the pins on the vibrotactile array that correspond to those pixels).

Results—Across all the studies, results have consistently shown that tactile image size and mapping ratios do have a significant effect upon an individual's ability to correctly recognize shapes and shape elements. No significant performance difference, however, has been found with ipsilateral (same-hand) versus contralateral (opposite hand) tactile feedback. This would indicate that there would not be any significant performance difference

between a system with the tactile array mounted on the movable puck and one with the puck held in one hand and the array felt with the other. If this finding holds true in more complex, realistic computer operation tasks, it could mean a lower cost approach for the development of the product by a commercial vendor.

Recent Publications Resulting from This Research

Development of Tactile Mice for Blind Access to Computers: Importance of Stimulation Locus, Object Size, and Vibrotactile Display Resolution. Wiker S, Vanderheiden GC, Lee S, in Proceedings of the Annual Meeting of the Human Factors Society, 1991.

[406] Computer Keyboard Overlays: Jumbo Keys

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Sponsor: National Institute on Disability and Rehabilitation Research; The Smith-Kettlewell Eye Research Institute

Purpose—The purpose of this study is to investigate ways of providing young children with low vision with an inexpensive presentation of large letters and other graphic material as a keyboard substitute for computer access.

Progress—Two different approaches for achieving our goal have been explored: 1) Jumbo Key Caps (large individual keys fitting over groups of two or more keys of a computer keyboard); and 2) graphic patterns drawn on existing flexible keyboard overlays designed to protect the keyboard from moisture (e.g., drooling). The present focus is on the second approach.

An exhaustive examination of keyboard configurations has been conducted and measurements of keyboard parameters have been made. Since there are literally hundreds of different keyboard configurations, modification of existing overlays is the most

economic approach. Clear plastic moisture guards provide us with an off-the-shelf "substrate" for graphic design.

Some moisture guards have been procured and their use tested with both an Apple IIC and a PC clone. The guards in no way interfere with striking multiple keys simultaneously (chords), as may happen in this graphic overlay approach. In addition, both computers responded to the chording by displaying each of the keys in the chord. This method of handling keys struck essentially simultaneously is expected to fit easily into the software development scheme needed for this project.

Future Plans—We plan to experiment with different paints and materials to develop a moisture guard that presents large surface areas of different colors. Software will be written to develop a simple color-matching program for children with low vision.

[407] Vocational Aids

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1. FAX-Based Reading System

Purpose—The purpose of this project is to explore a new way of aiding blind people in the task of obtaining access to printed information. Normally, this is accomplished by having a sighted person read the printed material to the blind person. Our system

extends this method to be both more convenient and timely by use of fax technology; the blind person "faxes" unknown material over the telephone to a "reader" who reads the document aloud over the phone. The existence of portable fax machines means that if the proposed system is realized, anyone can *at any time* have immediate access to

printed information. Human readers have the distinct advantage over reading machines—which incorporate optical character recognition (OCR) technology—for such purposes as communicating random documents (e.g., mail). The human reader can visually scan, evaluate, and describe the document quickly so that the blind person can make a decision as to its disposition (e.g., read completely, read account balance, or disregard document) efficiently.

Another important factor is that the expense of such a shared resource is very low compared to the high cost of hiring a reader on an individual basis (as is done now). The system also obviates the inconvenience of travel.

This *reader service* would benefit two target populations. Anyone with a print-reading handicap such as blindness, low vision, a learning disability or a reading disorder, could use the service to gain access to reading material. Those carrying out the service (the readers) need only be able to read, speak, and operate a telephone and push-button equipment; they may be homebound or restricted in their activity. This parallel thrust of promoting telecommuting for persons with mobility impairments (homebound) may offer a whole new world of job opportunities for the disabled. Success in implementing this system would also provide new worker resources for employers and a new market for communications and electronic firms.

Another potential application of this system is in public education. Unlike university-level education, where sighted readers for the blind students are provided by the Disabled Students Services of the university and/or the State Department of Rehabilitation, high school students are not provided reader access outside the classroom. The brailleing of a new textbook takes from 8 months to a year. Moreover, no mechanism exists for brailleing “temporary” documents such as class assignments, journal articles, magazines, newspapers, and other student reports. Timely access to this type of printed information using a fax reading service could fill large gaps in the information blind junior high and high school students are able to acquire.

Progress/Future Plans—The pilot study for the Fax Reader Project was initiated through the National Institute on Disability and Rehabilitation Research Rehabilitation Engineering Center (NIDRR-REC)

support and was completed toward the end of last year (see 1990 *Annual Report*). Those results were published in the *Journal of Visual Impairment and Blindness* in December, 1990. Following this, a limited 2-week informal field study employing five blind system users and a computer graphics (PC fax-modem card)-based reader station (operating with very restricted hours) was conducted to provide initial indication of the “real world” effectiveness of such a system. The outcome of the experiment was a definite improvement for users in convenient and timely access to print information. Several technical difficulties were encountered, and attention has been devoted to addressing these—particularly in improving the reader’s computer system to facilitate document handling.

The next phase will be a true real-world demonstration/experiment to establish the system’s utility for different users, patterns of use, types of material desired read, technical problems, and other data needed to prove the system’s feasibility in realistic conditions. In order to make this real-world testing possible, and as complete and valid as possible, we have sought outside funding. In July this year we were awarded a grant from the Easter Seal Research Foundation, which included partial salary support for two readers. We are currently working with our local Easter Seal Society to identify two of their clients who will act as readers for the project. The software to be used by the reader for displaying the fax information and for the direct, on-screen entry of survey information (e.g., type of document, reading transaction duration, etc.) into the project database has been integrated into a very user-friendly format. Data output available from this system includes pie charts of usage breakdown by type of document and similar information on system use and performance. The new project software has been installed on the two computers which have been configured with high-resolution, portrait-type monitors.

2. Multipurpose Braille Hardcopy Device

Purpose—The goal of this project is to improve computer graphics and print access by the development of new technologies in braille and graphics printing. The method under exploration is a novel thermal printing method which offers the potential

for fast, silent operation with greatly reduced numbers of moving parts.

Progress—During the past year, progress has continued as scheduled on the design and construction of a full-scale prototype system, capable of printing a full line of braille. The mechanical portion of the initial bench prototype is currently undergoing modifications designed to improve paper handling and contact between the thermal array and the vinyl substrate. Meanwhile, the circuit board design of the thermal printhead has been completed using a computer-aided design system.

3. Low-Cost Computer Access: "BATRUP"

Purpose—Computer access systems for the blind generally cost at least \$500 including the purchase of a speech synthesizer and screen review system. (Large print can be cheaper). Since the price of a relatively high-performance IBM-compatible computer system now hovers just around \$1,000, it becomes clear that the blind user, especially if he or she is young, starting out, and looking for work or training, is placed at an extreme disadvantage. That person not only has to add nearly 50% to the price of the computer, but also has to learn everything a sighted person does *and* how to run the access system.

Progress/Methodology—To better address the cost problem, we studied the feasibility of a "free" screen review program. This program would not be intended to compete with expensive commercial packages in features, packaging, advertising, or customer support, but would be sufficiently simple to use yet capable of accessing much commercially available software so as to give the new blind user a start without requiring a financial commitment which many cannot make.

A commercial speech synthesizer, the "Speech Thing," is available from Covox, Inc. of Eugene, Oregon as a part of several packages intended for the hobbyist sound-recording market. Costing only \$80, this synthesizer mostly consists of software, delivering digital output to the parallel port of the computer. The only hardware required is a passive A/D converter built into an adapter plug, and a small amplifier/speaker unit. While the speech is of good quality, its main disadvantage is its speed,

which cannot quite match that of most commercial devices costing \$200 to over \$1,000. However, its low cost makes it attractive for beginning users.

To fill the need for inexpensive computer access, our staff has been developing "Batrup," a screen access program specifically designed to operate with this synthesizer. This package will allow the blind user access to much commercial software, as in word processing, database systems, spreadsheets, and communications programs. The intended end user will need to purchase the Speech Thing synthesizer from Covox, and will then be able to have Batrup free through the privately funded Smith-Kettlewell Rehabilitation Engineering Service. Also, Covox has expressed interest in distributing Batrup with the Speech Thing package. As the system is developed, tested and perfected, it is intended that Batrup be available through computer bulletin board systems, catalogs, and through commercial software distributors who may wish to distribute it with "shareware" products.

As of September 1991, Batrup was nearly ready for preliminary distribution to several selected individuals who would test it thoroughly to assure that it does work as intended, and that it causes no damage to common applications.

In operation, Batrup and the software for the Speech Thing are loaded into the computer as "TSR" (terminate-and-stay-resident) programs. When this has been done with a simple command, the user may then run any text-based application program, which will operate normally. When the user wishes to examine the information on the screen put there by the application program, Batrup is "awakened" by pressing both the computer's shift keys. This unique combination assures that there is rarely a conflict between commands intended for the user's program and those intended for batrup. When these "hot keys" have been pressed, the program responds by saying "batter up." This tells the user that her application program has been frozen, and that she may examine the screen contents with Batrup. This is done mostly with the fingers of the right hand, which remain in the normal typing position. For example, pressing "k" causes the system to read the word which is under the computer's cursor. Pressing "K" causes that word to be spelled. Other commands allow the user to read around the screen by words, lines, or letters. The program also tells the user where she is

reading by row and column, and where the computer's cursor is, as well as information about highlighting and other attributes used by some applications.

4. Music Synthesizer Access

Purpose—The purpose of this project is to improve access by the blind to modern electronic music synthesizers and associated hardware and software.

Preliminary Results—As a result of input from us and other blind users of electronic music synthesizers, Voyetra Technologies now supplies, on computer disks, the manual for their SP GOLD sequencer program.

We have continued to test and demonstrate different sequencer programs and computer access systems in combination—examining their combined accessibility and devising solutions to access problems. Our music synthesizer/computer/sequencer system has been demonstrated at the California Transcribers and Educators of the Visually Handicapped at their conference, many of whose members were unaware that blind persons can gain access to such equipment using modern technology. At the RESNA conference, the system was demonstrated to members of the Trace Center REC, and potential use of the Trace SYSTEMS 3 access package for the Macintosh in application was discussed.

We have also explored access to software which prints music from MIDI data and which will also play back from a score after its data are entered in. A collaborator at the Berklee School of Music in Massachusetts, Jack Jarrett, has developed a program called Music Printer Plus for the PC. It does not utilize Windows, and in general, he wishes it to be easy for musicians to use. Voyetra Technologies is supporting his software, and he has expressed a keen interest in collaborating with us on making such a program usable for blind musicians (and other disabled musicians who must access the computer by means other than a keyboard).

Work has begun on an accessibility manual for blind musicians, to assist persons wishing to use modern synthesizer equipment in their jobs or pastimes. A complete issue of the *Smith-Kettlewell Technical File* is being prepared on this subject, and will be adapted for later separate publication and distribution to blind musicians.

5. Applications of Bar-Code Reading Technology

Purpose—We have begun exploring the possibilities of bar-code reading systems for the blind (as a means of identifying products, etc.). We see bar code readers as having three possible applications: First, there may be uses in vending stands operated by blind vendors where standard bar-code equipment, in conjunction with an on-site computer, could help in logging or keeping track of inventory. Second, a long-standing dream is that a blind shopper could bring a portable bar-code reader with him to the grocery store, whereupon he could shop independently; thus far, this is made unlikely by the fact that prices are peculiar to the store, and he would have to be connected by telemetry to the store computer to get price information. The third application is identifying food packages and other items at home; this machine could only identify because the cooking instructions or other directions could not be read with a bar-code device.

6. Digitized Speech Output for Talking Instruments and Equipment

Purpose—The "Nattering RAM" is a Smith-Kettlewell-designed, limited vocabulary, field-recordable speech board using only generic logic chips (to avoid the problem of specialized chip sets subject to obsolescence). It has features specially adapted for the blind user.

Progress—To date, several Nattering RAM boards have been built and have been added to other devices—for example, two "Talk-&-Tones" multimeters have been built, and two field-recordable talking street signs are being used in experiments in collaboration with the Department of Parking and Traffic of San Francisco. As an addressable speech recorder/player, the design of the Nattering RAM appears completely successful.

During 1991, a new speech product was announced by Information Storage Devices. These analog storage devices—a family of "message recorder" integrated circuits (ICs)—can greatly simplify the circuit design of field-recordable talking products. We have obtained samples of the new chips for evaluation in talking outputs for the blind. In order to preserve our circuit designs and instru-

ment interface protocols that use the Nattering RAM, we have successfully emulated the Nattering RAM (which contains 14 ICs) with this new product, the ISD1016, on a board containing only 2 ICs. The two boards are equivalent; they each have a ribbon cable that can be plugged into our front-end instrument circuits, providing a standardized speech interface.

The two speech boards compare favorably: the dynamic range of the ISD1016 is better than the Nattering RAM, but the recording is noisier (with background "pink noise") on the new device. There is no provision for a volume control in the ISD1016, but for many applications this is not important. The ISD1016 affords more recording time than the Nattering RAM, but the absence of a clock signal from this IC forces much of this memory to be wasted (for fear of running messages together and/or erasing them). (The Nattering RAM has clearly defined message slots which cannot blend together by mistake.)

The main disadvantage of this new IC is that there is no "second source" for it. If it turns out to be an unsuccessful product on the general market, or if subsequent versions are incompatible with this first version, use of it is a gamble that could render designs obsolete. The Nattering RAM, on the other hand, uses generic parts, which affords duplication of it anywhere that 8-by-32 k-byte RAMS and logic hardware can be obtained. It is also lower in cost (about \$39 versus \$79) in parts for the circuits.

Results/Implications—As a result of our efforts, there now exists a standardized interface protocol for talking instruments. Any design of noncomputerized talking instruments can now be done (using the protocol of the Nattering RAM) without fear of obsolescence, since we have emulated it with a new board. As long as it is an available product, use of the ISD1016 will be advocated in these applications; however, the two boards are completely interchangeable. Thus, future designs based on the ISD chip (using our interface protocol) will still be usable if the chip goes out of production. These efforts should help solve the past problems of obsolescence faced by talking instrument designs.

7. Flux-Gate Auditory Compass

Purpose—The Smith-Kettlewell auditory compass utilizing a Hall Effect sensor has been a useful aid for the blind. In contrast to locking-type braille compasses, this instrument provides the user with dynamic auditory feedback for determining direction and relative degree of veering from a desired path of travel. The purpose of this study was to redesign the original compass with regard to its size and cost.

Results—The use of the Hall Effect sensor has two drawbacks: the size (9 inches long) and the cost of the sensor (about \$100). We have redesigned the original compass using a flux-gate device. The flux-gate sensor dimensions are $1\frac{1}{2} \times 1\frac{1}{2} \times \frac{3}{8}$ inches, and its cost is about \$25. It can, because of its size, be mounted in the same enclosure as the circuitry for the compass. The enclosure we have used measures $4 \times 3 \times 1\frac{1}{4}$ inches.

In using this compass, the sensor (or, in this version, the box with the sensor in it) is oriented so as to achieve a null of the auditory signal; this occurs when the sensitive axis of the box is perpendicular to the earth's magnetic field (i.e., east-west). Rotating the unit in one direction causes a "beep-beep" signal, while rotating it in the opposite direction produces a "ding-ding" sound. One end can then be arbitrarily marked with tape so as to assign this end with a particular direction (our unit "beeps" when the tape end approaches north.)

We have designed and fabricated a printed circuit board for the new compass which is packaged in a pocket-sized enclosure. The Summer 1990 issue of the *Smith-Kettlewell Technical File* contains an article describing the construction of the flux-gate compass. The cost of parts for the compass in small quantities is under \$65. Several units have been distributed for evaluation.

8. Talking Signs™: Update on New Developments

Purpose—The Talking Signs™ orientation system for the blind was developed at the Smith-Kettlewell REC. It consists of infrared transmitters installed at

sign locations (intersections, doorways, entrances, elevators, etc.) which transmit preprogrammed messages which can be received by a blind pedestrian with an appropriate pocket-sized receiver. The stored messages are programmed (and heard by the user) as normal speech.

In the past year, two advances related to Talking Signs™ have occurred which have made it necessary for our staff to become re-involved with this project, supported by private Smith-Kettlewell matching funds.

Results—The City of San Francisco has ordered 20 transmitters for installation in the vicinity of Market, 5th, Powell, 5th Street North, and Cyril Magnin Streets.

For flexibility in experimentation, the first two downtown installations of street-name/signal indicators were made using Smith-Kettlewell's "Nattering RAM" boards. (This was done so that messages could be changed after feedback was received from members of the community who tried the equipment.) The experimental transmitters gave not only traffic signal and street name information, but also position in the crosswalk and direction in which the pedestrian was facing. These first two transmitters—facing each other to indicate the crossing of "5th Street at Market"—were left in place for 1 year. No degradation of LED output was apparent, and other than loss of modulation due to the intermittency of one of the RAM recorders, maintained power

output and survivability in "pedestrian header" enclosures proved completely satisfactory.

Future Plans/Implications—Love Electronics has developed an improved sign transmitter which dramatically increases the speech quality of the product. Meanwhile, this REC has just completed design of the control circuits and power amplifiers to be used with the new transmitters.

With the emergence of the new transmitter, a new recorder is necessary to program the EPROM chips which contain the messages. In collaboration with Love Electronics, we have undertaken this development project. The new device will be able to record from one to eight separate words using the standards of the new transmitters. This speech recorder/programmer will also be of use in other speaking devices under development at Smith-Kettlewell, such as offshoots of the Nattering RAM technology. The unit is now almost complete and will be ready for service by the end of 1991. The REC will continue to be involved where customized and/or experimental installations are made.

Recent Publications Resulting from This Research

The Nattering RAM: A Sixteen-Word, Field-Recordable Speech Board. Fowle W, et al., in Proceedings of the 13th Annual RESNA Conference, Washington, DC, 263-264, 1990.

The Use of Fax Technology to Address the Reading Needs of Blind and Visually Impaired Persons. Gerrey W, Brabyn J, Crandall W, J Vis Impairm Blindn 509-513, December 1990.

[408] Low Vision

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Sponsor: *National Institute on Disability and Rehabilitation Research; The Smith-Kettlewell Eye Research Institute*

1. SKILL Chart

Purpose—The goal of this project is to design, evaluate, and disseminate a novel low-contrast, low-luminance acuity chart designed to test the visual system under more realistic adverse conditions than the conventional Snellen-type acuity tests.

Methodology—This goal is being accomplished through the development of the SKILL (Smith-

Kettlewell Institute Low Luminance) Chart—a near acuity chart using modified ETDRS letters, printed in black on a dark gray background with a contrast of 15%. This simulates low-luminance, low-contrast conditions in the clinician's office without controlled manipulation of lighting (not practical in real clinical practice). Our hypothesis is that the test, as a screening tool, will allow early detection of macular disease and enable separation of deficits in contrast sensitivity due to media opacities versus retinal

dysfunction. This will allow the average (non-low vision specialist) clinician to detect early retinal changes (which do not show up in the usual tests but which cause real handicaps) and recommend suitable rehabilitative measures and/or refer the patient to a low vision clinic.

Progress—Ten prototype SKILL Charts were distributed to and evaluated by local clinicians. This evaluation was intended as a test of the practicality of the chart rather than as a scientific study of vision test results; our goal was to obtain feedback from clinicians regarding the ease of use of the new test and the manner in which it would fit into the existing clinical routine.

The resulting feedback has led to a number of suggestions for incorporation in future versions of the chart. The photographic method of production currently utilized provides an excellent nonreflective surface at high resolution; however, the surface is subject to finger marks—resulting in a need to replace the chart after prolonged use. New methods of production must, therefore, be found. Maintaining a constant test distance while reading both the dark and light sides of the chart was also found to be a problem in some cases; this will be solved either by using clearer instructions or by attaching a short cord to the card for establishing the test distance to the patient's forehead (a method used in other near tests such as the Lighthouse near vision reading test).

In general, the new packaging of the chart was met with favor by the clinicians. This packaging utilizes a low-contrast, low-luminance SKILL Chart on one side—with a high-contrast, high-luminance version of the same chart on the obverse side. A different letter sequence is used on the obverse side so that memorization of letters cannot assist the patient. In addition, a border is placed around the card on each side—providing a convenient hand-holding surface for the patient, while protecting the SKILL card from physical damage.

Preliminary Results—In pilot testing of the SKILL Chart, it has been found to possess unique predictive value in relating vision to real-world performance. In our low vision reading study, scores on the SKILL Chart correlated more highly with reading performance than did any other test. Similarly, in our recent study on low vision and driving

performance (see section 4 in this report), the SKILL test was one of the few that has ever been shown to correlate with accident rates in driving.

Additional data from 88 patients have been collected during the past year in collaboration with Jose Pico, MD, and Robert Stamper, MD, to explore the use of the SKILL card in monitoring and predicting progress of glaucoma. The SKILL card was used to assess the integrity of the foveal region in a group of individuals with ocular hypertension who are at risk of developing chronic open-angle glaucoma as well as other groups of patients already diagnosed as having glaucoma. A control group with no ocular disease was also included.

[Note: The SKILL score refers to the number of lines of visual acuity lost when switching from the standard high-contrast, high-luminance chart to the SKILL card with its low contrast and low luminance.] There was a gradual increase in the score with increasing severity of the disease. The larger the score, the worse the acuity on the SKILL card. The advanced glaucoma patients lost an average of 7.2 lines on the SKILL chart compared with standard acuity, which means that their average visual acuity decreased from 20/30 to about 20/180.

An important point regarding the glaucoma suspects was the bimodal nature of their SKILL score distribution. A very small percentage of suspects go on to develop glaucoma; thus, we expect the majority of the suspects to have normal function (which they do). The challenge in current research relating vision function and glaucoma is to identify those patients most likely to go on to develop the full-blown disease. It is tempting to speculate that those suspects who show more than five-lines loss on the SKILL card are more likely to develop glaucoma.

Future Plans—Follow-up studies are planned in order to test this hypothesis.

2. Visual Field 'Remapping'

Purpose—The concept of visual "warping" or "remapping" involves moving the image on the retina out of the "blind spot" or scotoma and displaying it in adjacent parts of the visual field. This idea has been advanced by engineers at NASA as a possible rehabilitative mechanism for low vision persons, using sophisticated image-processing hard-

ware and software in combination with electronic displays.

Methodology—We anticipated certain difficulties with this concept when applied in clinical practice; in order to test the idea at low cost and explore the problems and possible solutions with low vision patients, we devised a biprism remapper. The device uses simple optics, which can displace text so that it falls outside the blind spot (which corresponds to the gap between two prisms placed base to base). This device may offer an inexpensive alternative to the electronic approach, as well as a means to test the feasibility of the remapping concept.

Progress—This year, we engaged the services of a low vision Fellow (Simon Warner, MD) in collaboration with August Colenbrander, MD, of our affiliated low vision clinic. Dr. Warner constructed two prototypes of the biprism remapper; one designed to be attached to standard optical magnifiers and one for attachment to a CCTV reading aid.

Initial pilot testing in the low vision clinic has yielded mixed results; as we hypothesized, adjustment to such remapping is not an entirely natural function, and patients appear to require time to become accustomed to it. In addition, the model assumed by the remapping concept (i.e., that scotomas are black holes) is seldom true in practice, and this fact is bound to reduce the range of applicability of the concept.

Future Plans—Pilot experimentation will continue, in order to allow an assessment to be made of the feasibility of the remapping approach. We plan full sharing of results with the NASA researchers working in conjunction with the Wilmer Eye Institute on the sophisticated image processing/remapping project.

3. Illumination Aids

Purpose/Progress—The spectacle-clip illuminator developed by this Rehabilitation Engineering Center (REC) and described in our previous report is now entering the research utilization phase. Contacts with suitable manufacturers are being sought to explore the feasibility of commercial production and distribution.

Work has begun on a second illumination

device, originated by Alan Scott, MD, of Smith-Kettlewell, which combines both magnification (+10 diopters) and illumination in a self-contained spectacle clip-on device. The device allows binocular viewing at high magnification powers through the incorporation of base-in prisms, and has a total weight of approximately 30 grams including battery. Design is in a preliminary stage, with several prototypes and modifications under evaluation.

4. Driving and Vision Impairment Study

Purpose—It has been demonstrated that older drivers are involved in the highest number of traffic accidents per mile driven and are judged to be at fault more often than any other age group.

Standard high-contrast Snellen acuity and other conventional eye tests do not accurately predict difficulties in driving performance experienced by the aged and those with minor visual impairments. In some cases, even though Snellen acuity might be 20/20, loss of contrast sensitivity under low illumination, reduction in color discrimination, or inability to rapidly recover from glare can present potential driving hazards.

These subtle but important visual deficits occur frequently in the early stages of macular disease (which is now the most common cause of new cases of visual impairment in the elderly), and some also occur with developing cataracts, even before a substantial loss in acuity is found.

Under supplementary funding from the California Department of Motor Vehicles, we conducted a study to relate vision functions which are known to decrease with aging to decrements in driving performance.

Methodology—Using a battery of functional (practical, low cost) vision tests designed specifically to predict visual performance, we compared vision test scores with the driving records of 97 drivers over 55 years of age. Half of the group had no accidents in the last 3 years while the other half had three or more accidents. The vision test battery included visual acuity under high contrast and low contrast conditions as well as low contrast-low luminance conditions, peripheral visual fields with and without attentional demand, contrast detection for larger targets, sensitivity to disability glare, recovery from exposure to glare, and color vision.

Results/Implications—Several visual skills that are known to decrease with age were found to be reduced in the accident-prone subjects. The skills with the strongest statistical relationship to accident involvement included low contrast-low luminance visual acuity, disability glare, and the extent of the standard visual field directly down and to the right or to the left. The most highly accident-prone subjects also showed reductions in contrast sensitivity, and their visual skills showed larger vision decrements than the moderately accident-prone drivers.

On the attentional visual field test, there tended to be a sharp drop from those with no accidents to those to those having had accidents. It was not a steady graduation as there was in the regular visual field; this may be a test with more discriminating power.

There was a significant reduction in contrast sensitivity in those people with the highest accident-proneness index. Significant differences were also found in all analyses of the disability glare test.

These results are remarkable in that previous studies of vision and driving—using conventional tests of vision—have generally failed to show any strong correlation between accident rates and vision. The new, more subtle and realistic tests utilized in our study, were able to pick them up, using vision function not noticeable on standard tests. In addition, the number of subjects in our study was very small compared with previous studies on driving, making it even more remarkable that statistically significant differences were found.

It may be that only people with the most severe vision decrements contribute significantly to accidents. So as an adjunct analysis, we compared the people with the 10 worst scores to the people with the 10 best scores on each test. We found that people with the worst scores on the attentional

visual field, standard visual field, and bright glare tests were several times more likely to be in the accident group than in the nonaccident group.

People who wore bifocals were also more likely to be in the accident group and at fault than people with only single-vision correction lenses. If this observation is found to hold up in larger samples, and under more study, perhaps people could be advised to use single-vision lenses while driving, or further research could indicate what the problems are when using bifocals. In our study, as in previous work, standard acuity tests did not correlate at all with any of the driving measures evaluated.

The fact that the new REC-developed vision tests (designed to simulate real-world visual tasks and detect practical handicaps) were predictive of driving performance was encouraging. It appears that the new tests, in contrast to the traditional Snellen-type acuity tests and other currently used methods, relate more closely to real-world task handicaps.

We are currently working with the California Department of Motor Vehicles, in a larger scale study within the DMV driver testing sites, to incorporate several of these tests as a screening procedure. It is envisaged that the results would be used to alert drivers with vision defects to the problems they may encounter while driving.

Recent Publications Resulting from This Research

Smith-Kettlewell/CALDMV Vision Test Project. Brabyn J, Summary of Proceedings of the Conference on Driver Competency Assessment, California Department of Motor Vehicles and Transportation Research Board, National Research Council, San Diego, CA, 52-54, October 1990.

Vision Performance and Accident Rate in Older Drivers. Brabyn J, Steinman B, Portnoy G, in Proceedings of the National Conference on Driver Competency Assessment, California Department of Motor Vehicles, San Diego, CA, October 1990.

[409] Assessment of the Need for a National Information and Referral Center for Individuals with Partial Sight

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Sponsor: National Institute on Disability and Rehabilitation Research; Mississippi State University

Purpose—The purpose of this project was to conduct a study to clarify definitions of low vision, the characteristics of the partially sighted population, the service needs of the partially sighted population, and to define and identify services available.

Progress/Methodology—Questionnaires/survey instruments were developed and completed by 54 state vocational rehabilitation agencies, 112 low vision clinics, 48 client assistance projects, and 366 legally blind and partially sighted consumers.

Results—A large proportion of the partially sighted consumers surveyed were not aware of client assistance projects or the services they provide. A variety of implications are discussed in the final document with regard to impact upon vocational rehabilitation agencies; likewise, a variety of recommendations are presented with regard to additional actions that should be initiated to improve the information and referral services made available to partially sighted individuals.

[410] Identification and Classification of the Career Transition Problems of Blind and Visually Impaired Persons Employed as Professionals, Managers, or Technicians

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Sponsor: National Institute on Disability and Rehabilitation Research; Mississippi State University

Purpose—The purpose of this project is to identify and classify the career transition problems of adults with visual impairments employed in professional, technical, or managerial jobs.

Progress/Methodology—A nationwide sample of 213 adults (23 to 79 years of age) with visual disabilities agreed to participate in a telephone interview. The respondents answered questions about their careers and the perceived effects of their visual disability on their careers.

Results/Implications—Rehabilitation counselors must

increase their awareness of the nature, impact, and time frame of the problems commonly faced by people with visual disabilities. Rehabilitation counselors can provide assistance during the rehabilitation process that will help clients prepare for problems that will occur after job placement. This assistance will help people with visual disabilities to develop strategies at all career stages that will prepare them to take advantage of career advancement opportunities. Full participation in the labor force, including access to upward mobility, is the goal of rehabilitation services for people with visual disabilities.

[411] Identification and Classification of the Career Transition Problems of Blind and Visually Impaired Youth in Transition from School to Work

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Sponsor: National Institute on Disability and Rehabilitation Research; Mississippi State University

Purpose—The purpose of this project is to study the transition of youth with visual impairments from school to work in order to identify career transition problems and solutions.

Progress/Methodology—The project had two major components. The first was a literature review of the career development of youth in transition, theories of general youth development, youth career development problems, and career development of youth with visual impairments. The result of this component was a publication featuring annotated bibliographies of selected readings.

The second part of the project was a qualitative study of transition programs. Two noted transition programs were identified, one school-based and the other rehabilitation-based. Administrators at those programs selected 12 people who were between the ages of 16 and 27, who had participated in transition programs, and who were still in training or were currently employed. Interviews were organized around client clusters: 1) the youth in transition; 2) parent; 3) rehabilitation teacher; 4) rehabilitation counselor; 5) employer; and, 6) other people playing significant roles in the transition process. A total of 53 people were interviewed for the 12 client clusters.

The semi-structured interview forms included questions about client characteristics, educational components, transition services, housing and transportation opportunities, and employment concerns. A semi-structured interview format was selected for this study because it allowed wording and directions to be changed as necessary. To verify the information, the researchers compared notes for each interview. Questionable data were rechecked on site by questioning rehabilitation or educational personnel. Programmatic components were verified through examination of institutional literature and case records and by questioning program directors and administrative personnel.

Results—Data were coded and analyzed. The following conclusions were reached: 1) respondents who are developmentally delayed and who are also employed in sheltered workshops received the fewest services; 2) no particularly identifiable set of factors lead to employment; 3) the key to successful transition from school to work appeared to be carefully selected services planned by a number of persons concerned with each client, including both the client and parents whenever possible; and, 4) someone must take a primary responsibility for the planning, but the stronger the involvement on the part of all participants, the more positive the outcome seems to be.

Future Plans—We are initiating a new project entitled, "Transition to Work: Students with Visual Impairments in Post-Secondary Educational Institutions." The purpose of this research will be to identify skills, knowledge, and steps necessary for students with visual impairments to successfully make the transition from high school to post-secondary educational institutions for the purpose of advanced training in order to successfully compete in the job market, and to successfully make the transition from post-secondary institutions into the workplace.

Recent Publications Resulting from This Research

Transition from School to Work: Youth with Visual Disabilities (Technical Report). Tedder NE, McBroom LW, Kang J, Mississippi State, MS: Mississippi State University, Rehabilitation Research and Training Center on Blindness and Low Vision, 1990.

Youth with Visual Disabilities: Transition from School to Work (Selected Readings). McBroom LW, Tedder NE, Kang J, Mississippi State, MS: Mississippi State University, Rehabilitation Research and Training Center on Blindness and Low Vision, 1990.

Transition from School to Work: Youth with Visual Disabilities (Executive Summary). McBroom LW, Tedder NE, Mississippi State, MS: Mississippi State University, Rehabilitation Research and Training Center on Blindness and Low Vision, 1991.

[412] Identification of Differential Costs and Time Usage of Blind and Visually Impaired Persons

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Sponsor: National Institute on Disability and Rehabilitation Research; Mississippi State University

Purpose—The aim of this project was to answer the following research questions: Are there differential monetary costs and time utilization patterns for persons who are blind or severely visually impaired? In what categories do these different costs occur, and are they associated with particular life styles, life stages, and environments? Are there relationships among the differential expenditures and time usage patterns associated with blindness and visual impairment and the rehabilitation process?

Progress/Methodology—Telephone interview forms were used to collect information from 227 blind or visually impaired persons and 152 sighted persons (379 total respondents). During the initial telephone contact, respondents were asked questions about their vision loss, health problems, methods of reading, and use of readers. Sighted peers were identified by the visually impaired respondents at this time. During the next four interviews, the 379 respondents were asked about personal care activities and assistance, mobility and transportation, aids and adaptations, education, employment history,

household members, type of community, life satisfaction, use of vocational rehabilitation services, and income. Four time diaries were used to solicit information about how that person spent time during the previous 24 hours. Time diaries were balanced by day of the week and season of the year.

Results—Data has been coded and analyzed resulting in numerous presentations during the last year. Results show that visually impaired respondents are involved in a wide variety of activities with little restriction on their range of activities. Sighted respondents tended to spend more time in child care, obtaining goods and services, attending to self-care activities, and engaging in social activities, while visually impaired respondents spent more time in educational and passive activities.

Future Plans—We will use the results from this study in the related study, "Differential Costs and Time Usage of Visually Impaired Persons and the Vocational Rehabilitation Process."

[413] Improving and Expanding Social Interaction Skills of Youth with Deaf-Blindness in Supported Employment Settings

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Sponsor: Office of Special Education Programs, U.S. Department of Education; Perkins School for the Blind

Purpose—The purpose of this study is to categorize the kinds of interventions that are designed by an expert team to facilitate the work adjustment of deaf-blind students.

Methodology—The method involves a time-series design incorporated into case studies. Each student had an "expert team" comprised of teacher, job coach, etc., who observed typical examples of the

student's situation at work. The team designed any necessary interventions. A thematic analysis will determine whether there are common modifications made across students and whether most modifications are made regarding the student's behavior or accommodations in the workplace.

Progress/Results—Instruments were developed for use by expert teams to rate videotaped behavior of deaf-blind students in vocational settings.

The project is in the data analysis stage. No results are available to date.

[414] Validation of Instructional Practices with Youth Who Are Deaf-Blind

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Sponsor: *Office of Special Education Programs, U.S. Department of Education; Mississippi State University*

Purpose—The purpose of this study is to identify modifications in instructional practices that are necessary for use with deaf-blind students by observing changes in teacher-student interactions.

Progress—Published instruments were selected for pre- and post-measures. Instruments were designed to collect demographics and teacher self-efficacy ratings, and to record observations of teacher-student communication. Data collection has been completed at six sites. The teacher-student communication instrument has been described in a journal article that is in press.

Methodology—The method involved a time-series design incorporated into case studies. This project involved rating communications between teacher and student, pre- and post-tests of teacher job satisfaction, ratings of teacher self-efficacy before and after intervention, and teacher design and use of specific adaptations in instructional strategies in order to teach a deaf-blind student.

Results—This project is in the data analysis phase; no results are available to date.

[415] Mobility Assistants—A Training Videotape: Topics for Working with Multiply Impaired Persons

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Sponsor: *Perkins School for the Blind*

Purpose—A 14-minute videotape was produced to be used as a supplement to the curriculum that has been developed to train a new entity of workers for the blind who are called "mobility assistants." The curriculum was developed to provide support personnel for orientation and mobility specialists who teach visually impaired individuals to travel independently. The curriculum, with the videotape, was distributed nationally through a training program: it is the first of its kind on the topic of mobility assistants.

Progress/Methodology—A videotape entitled *Getting There . . . Safely and Independently*, is completed and has been enthusiastically accepted by the sponsors. The script for the videotape was developed by blindness and video professionals and was completed with the joint efforts of videotape and camera professionals and blindness consultants. Visually impaired children and adults were recruited to act in the video.

Results—The videotape is being used in workshops across the country, and is receiving positive com-

ments regarding its need in the field, as well as its content.

[416] Differential Costs and Time Usage of Visually Impaired Persons and the Vocational Rehabilitation Process

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Purpose—The purpose of this project is to answer the following question: Are there relationships among the differential expenditures and time usage patterns associated with blindness and visual impairment and the rehabilitation process?

Progress/Methodology—Data has been collected on 120 subjects from four state rehabilitation agencies. These subjects were in status 00 through 30 of the rehabilitation process (referral, diagnostic evalua-

tion, service provision, and placement). The data has been coded and analysis has begun.

Case file information on fiscal, demographic, and service data was collected in a format compatible with existing RRTC data sets. Telephone interviews over two time periods using refined time usage and cost data instrumentation were used to collect information directly from the 120 subjects.

Future Plans—Future plans are to complete the project and make the results available.

[417] The Head Reader: An Audio-Tactile Display for Blind Lawn Bowlers

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Sponsor: *Royal Society for the Blind of South Australia*

Purpose—The sport of lawn bowls is suitable for blind sports lovers because it is a competitive sport requiring concentration and accuracy without the need for fast reflexes, high levels of hand-eye dexterity, or a wide-ranging movement. Currently, blind lawn bowlers rely on a sighted helper to interpret the bowls "head" (the head is the loci of bowls surrounding the target jack at the other end of the green). To increase the enjoyment and independence of these bowlers, a product will be developed that enables the blind bowler to "see" and interpret the game situation for her/himself. This product, "The Head Reader," will use an audio-tactile feedback combination to describe the head.

Methodology—The prototype Head Reader uses a video camera mounted above the green to "grab" an image of the bowls after the delivery of each bowl. The image is transmitted (UHF) to a trolley-based personal computer and processed to extract relevant bowl coordinate and ownership information. The blind bowler will then use a modified Braille mouse (a standard PC mouse with a number of 4×2 pin electronic Braille cells suitably mounted in finger positions) to scan across a board representing the head. As the mouse moves across the board, the mouse pointer moves across the screen. The Braille cell finger pads highlight the location of bowls. An inexpensive speech synthesizer board provides a more accurate description of the location

of the bowls, and provides other functions such as a talking score-board, clock, and rules book.

Progress—A prototype Braille mouse and Braille cell driver have been developed. Software is being written to integrate the frame grabber, speech synthesizer, mouse, and Braille drivers in the C

language. A working model will be available for testing during the forthcoming bowling season.

Implications—The Head Reader will be accessible to rehabilitation specialists for patients with other handicaps such as spinal cord injuries and brain damage. The system will possibly have many applications outside of the sport of lawn bowling.

D. Deaf-Blind

[418] Second-Generation Mechanical Hand Communication Aid for the Deaf-Blind

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Sponsor: VA Rehabilitation Research and Development Service (Core Funds)

Purpose—A solution to communication problems that deaf-blind people experience is offered by "Dexter II," a second-generation computer-based electromechanical fingerspelling hand. This device enables a deaf-blind user to receive tactile messages from the mechanical hand in response to keyboard input during person-to-person communication, as well as gain access to computer-based information.

Progress/Methodology—This work is a continuation of a 1985 project in which four graduate Stanford mechanical engineering students designed and fabricated a mechanical fingerspelling hand. A major goal at that time was to develop a system with easily modifiable finger positions. This quality was realized in the completed project, a new robotic fingerspelling hand named "Dexter."

A more compact version of the original Dexter mechanical system was designed in spring 1988 by three graduate mechanical engineering students. Their design, Dexter II, employs DC servo motors to pull the finger drive cables of a redesigned hand, thereby eliminating the need for the pneumatic power source. A speed of approximately four letters per second (almost twice that of the first design) can be achieved with the improved device.

In operation, a message is typed on a keyboard (an Epson HX-20) by an able-bodied person. The

ASCII value of each letter is used by the software as a pointer into an array of stored control values. This data programs pulse-width modulation chips which operate the eight DC servo motors in Dexter II. These motors then pull on the drive cables which are the "tendons" of the fingers, producing finger flexion. The hand configuration is felt by the deaf-blind communicator and interpreted as letters of a message.

Although neither Dexter nor Dexter II can exactly mimic the human hand in fingerspelling all the letters, they can display close approximations that are easy to learn by the deaf-blind user.

Results—Deaf-blind clients of Lions Blind Center (Oakland, CA) served as subjects for the initial testing of Dexter. They were able to identify most of the letters presented by the robotic hand without any instructions, and in less than an hour were correctly interpreting sentences. Equally important was their positive emotional reaction to the hand. They seemed to really enjoy using it and to be intrigued by its novelty. There were no negative comments made concerning its mechanical nature or any other aspect of the system.

Dexter II was first tested by a deaf-blind person who is extremely proficient at receiving tactile fingerspelling. She provided many suggestions for

improving Dexter II's letter-shape configurations. Later, it was introduced to 12 deaf-blind people during an annual retreat. About 20 deaf-blind attendees at the annual Deaf-Blind Conference in Colorado Springs in June 1989 had a chance to experience Dexter II. The device was also exhibited at the RESNA '89 Conference in New Orleans and at the InvenTech meeting in Anaheim in September 1989. The ability of deaf-blind individuals to initially understand Dexter II varied considerably.

Future Plans/Implications—Dexter is intended to serve deaf-blind users as a complete receptive communication system, not just a means of receiving information in face-to-face situations. Its ability to respond to computer input means it can be interfaced to a TDD to provide deaf-blind people with telephone communication. It can also be connected to computers to provide expanded vocational and avocational opportunities for the deaf-blind community.

[419] Research for the Multihandicapped

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Sponsor: *National Institute on Disability and Rehabilitation Research; The Smith-Kettlewell Eye Research Institute*

Purpose—We are exploring a multidisciplinary approach to the rehabilitation of the multihandicapped population. The goal is to develop innovative methods to refine diagnosis, prognosticate developmental anomalies, and devise optimal rehabilitative strategies for the multifaceted problems of vision/hearing handicaps and cortical blindness.

Progress—The principal thrust of this work during the current year has been collaboration with Helen Simon, PhD, the research audiologist on our staff at Smith-Kettlewell—and her project team. The goal of this work is to develop an objective method of monitoring each channel of the subjects' binaural hearing system—a method applicable to adults, infants, and communication-impaired persons. This will provide us with an analog—in the hearing domain—of the photorefractive and visual evoked potential methods we have already developed for vision. In addition, the system will measure interaural timing differences or "phase coherence" which may be abnormal in those with asymmetrical hearing impairments.

Preliminary Results—The development of an auditory evoked potentials system for acquisition and analysis of data has been completed and the system is currently being used. A DSP32-C-based digital-signal-processor add-on board is used in a PC-386 to collect responses to amplitude-modulated tones. Stimuli are generated and data are processed in

real-time at 50K Hz per channel. Further data analysis takes place off-line. The system is initially being used to evaluate the monaural and binaural response variances in a sample of normal-hearing adult subjects.

Future Plans—Further enhancements to the system are being planned and include better data handling methods and user interfaces.

Other research in the area of the multihandicapped:

1. Survey of Deaf-Blind Consumer Needs

Purpose—Since deaf-blindness impacts on so many aspects of one's life, it is important to get a picture of which of the many problems this population experiences as most severe, but which have the potential to be addressed by technology. Toward this end, Dr. Gilden developed the Deaf-Blind Technology Needs Questionnaire which asks both global and specific questions concerning technology needs, and gives the respondent an opportunity to be as constricted or expansive, confined or creative, as he or she wishes. It also incorporates specific questions about taking medication which will help guide us on how to proceed with the vibrating medication timer project.

Preliminary Results—The data from the 11 questionnaires completed this year have come from

individuals who have no useful vision or hearing. All 11 own at least a Wristcom and a braille watch, 9 own a braillewriter, and 7 have a TeleBraille or a TDD. This suggests individuals who are in a program with good technology awareness and good resources, as well as a significant level of technology sophistication among themselves.

As with the previous year's respondents, this group also expressed much concern over not knowing what is available to help them. The specific requests for technology that they did make are an interesting combination of low tech and high tech needs. For example, while there were requests that could be answered by simple braille labels and braille books, there were also requests for devices that could assist with orientation and mobility, and for devices that could provide access to radio, television, movies, and newspapers. The need for less expensive technology was also expressed.

The Deaf-Blind Technology Questionnaire will be administered to more individuals until at least 50 are completed.

2. DEXTER III

Progress/Implications—*New Hand Design.* Dexter is a robotic fingerspelling hand for the deaf-blind, initiated by this Rehabilitation Engineering Center (REC). Earlier versions of Dexter were developed in collaboration with the VA Rehabilitation Research and Development (RR&D) Center, Palo Alto, CA, and with Stanford University. Last year, a new anthropomorphic hand was designed and built by Upstart Robots (who are conducting advanced development—with continued consulting and collaboration by our staff—with a view to commercialization of the project). One of the problems of the previous hand was the lack of a home position where the exact location of all the phalanges was known when the drivers were powered up or down.

The new hand automatically opens to a fully extended gesture when the drivers are turned off; consequently, the software can depend on knowing the fingers' starting positions. Additionally, and also the most difficult to obtain, the fingers center themselves halfway between fully abducted and fully adducted positions when the power is turned off.

It is anticipated that the drivers will be independently turned off frequently during the formation of the letters, since many letters use fully extended

finger positions in their letter formations, thus assuring frequent adjustment of software versus actual positions.

New Driver Design. With input from our staff and others, a new driver design has been developed. This uses stepper motors to drive the tendons directly. There are no gears and consequently no gear inertia. When any one of the 16 motors is powered down, springs return the motor back to a mechanical stop, thus defining an exact "home" position. The motors are a standard form factor M25 so that a variety of off-the-shelf and surplus motors can be tried, thus helping to contain costs. The larger motors will have greater pulling force for the hand and should increase the speed of fingerspelling.

Improved electronics have been designed. Upstart Robots decided to use Bipolar Driver circuits because of their superior power-to-weight ratio over the unipolar variety. We are also using an improved microprocessor chip, the Dallas Semiconductor DS5000, which has embedded lithium battery backup. This microprocessor will be able to remember fingerspelling gesture edits, which will help in the development stages. Since the earlier capstan drive also used stepper motors, the old software will transfer to the new design.

3. TELEBRAILLE II

Purpose—The TeleBraille is a TDD for use by deaf-blind persons. It has a braille display as well as the standard visual display. The Smith-Kettlewell REC has developed the new TeleBraille II, which is now being put into production by Telesensory. This project was necessitated by the obsolescence of the old TeleBraille, which ceased production in 1988 because the modem upon which it was based became obsolete and unavailable. The small market for such devices made a new design effort uneconomic for Telesensory alone; consequently our REC became involved in the design phase and managed all aspects of the project except where production-related questions were involved.

Progress—After soliciting input from deaf-blind users of the old instrument, and establishing the new features desired by the user population, the approach taken in our design was to utilize the Telesensory "Navigator" (a volatile braille display

system) and the Ultratec Supercom (a TDD with a modern microprocessor-based modem) as a basis for a new system—with appropriate hardware and software modifications. Details of the new design are being prepared for publication and presentation for the upcoming World Congress on Technology. During the past year, as the project neared completion, the following steps were undertaken:

Smith-Kettlewell: Complete new firmware for "Navigator" box to support all TeleBraille and Supercom functions. Complete and update interface definition with TDD. Design modifications to navigator hardware to allow support of printer output port. (Printing functions which were originally in Supercom moved to braille box.) Complete newly written TeleBraille users manual.

Our collaborators in this project also undertook the following functions:

1. **Telesensory:** Complete design of braille keyboard to fit their "Navigator" braille display box. Complete design of adapter plate to hold TDD (Supercom) atop navigator case. Specify and obtain appropriate power supply. Design carrying pack and shipping packaging.
2. **Ultratec:** Complete modifications to Supercom TDD firmware to meet Smith-Kettlewell definition document. Complete design of Serial interface board and cable for Supercom to connect to Navigator box. Complete power wiring modifications to Supercom to make it compatible with Navigator power supply.

After a brief beta test period and initial modifications, production units were first shipped to customers by Telesensory in approximately January 1991. While firmware bugs found in early units were being attended to, we took the opportunity to add several minor features, such as the ability of the system to maintain the on/off status of the printer if the braille box batteries failed in mid-operation. Also, a command was added which allows the braille reader to skip messages received in "Autoanswer" mode with the braille display. Previ-

ously shipped units were repaired and updated accordingly.

Meanwhile, our staff revised the manual both to add further clarification and to document the newly added features which were added to the braille firmware.

Reaction from first-time users has been most positive, as they gain access to communications which they have never before experienced. Reaction from users of the original TeleBraille (which ceased production in 1988) has also been positive; most people who are at all familiar with computerized products indicate that they find the unit functional and convenient, they appreciate the new features incorporated in the system, and many have said that the manual (written entirely by our staff) is one of the best they have seen.

Results—As a result of the Smith-Kettlewell led design and development effort, a new and greatly improved TeleBraille is now on the market, and appears to be well received by its market population.

Because of the design choice of modern microprocessor-based TDD and braille display units, and the use of a relatively simple standard interface (serial RS232C communications) between them, future upgrades of this basic machine will be less traumatic than this one. Much of the work required for this unit should be transferable to more modern units when obsolescence makes that necessary.

Recent Publications Resulting from This Research

Braille Computer Screens: A New Perspective. Gilden D, Orlosky S, in Proceedings of the Second International Conference on Computers for Handicapped Persons, Zurich, Switzerland, December 1990, 101-113.

Hand in Hand With Dexter: A Robot for Communicating With the Deaf and Blind. Gilden D, presented at the Conference on Computer Technology for People With Special Needs, University of Auckland, Auckland, New Zealand, January 26, 1991.

Some Sensory Aids from Smith-Kettlewell Rehabilitation Engineering Center. Gilden D, presented at the National Society for the Blind, Sydney, Australia, January 16, 1991.

XV. Spinal Cord Injury

A. General

[420] Factors Influencing Joint Compliance and Reflex Mechanisms Following Spinal Cord Injury

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Sponsor: VA Rehabilitation Research and Development Service (Project #B446-RA); Paralyzed Veterans of America

Purpose—Spinal cord injury generally alters the normal pattern of motor control, often in unpredictable fashion. Reflex activity can be measured by studying how the stiffness of the agonist and antagonist muscles about a joint changes with volitional contraction, muscle length changes, and limb perturbation. Unfortunately, direct stiffness measures of all muscles involved requires invasive measurements. One can, however, focus on the joint itself and measure its compliance, which includes the stiffnesses of the individual muscles.

Methodology—We measure joint compliance by perturbing the ankle. We provide either precise angular or torque perturbations using a computer-controlled torque motor. Joint angle, acceleration, torque, soleus, and tibialis anterior electromyograms are digitized and stored by the computer. We use these samples of angular torque, angular acceleration, angular displacement (from which we also derive velocity) to determine by least-squares-fit the moment of inertia (J), the damping coefficient (B), and one or more spring coefficients (K) over specific portions of time. Compliance can be measured using various perturbing frequencies or in the time domain by application of a disturbing signal such as a step or ramp (constant velocity) input. Also, neurologically intact and partially impaired subjects can “tense up” their muscles at different levels to overcome differing bias torques, thus changing muscle stiffness and hence joint compliance. Thus, compliance must also be tested at different levels of bias torques. Finally, the torques to overcome a bias

can be produced by surface electrical stimulation of the appropriate agonists, even in those subjects with a tonic paralysis. Neurologically intact subjects as well as spinal cord injured (SCI) subjects are tested.

Results—In intact subjects, B and K were relatively constant across all velocities (second order model), while in many of the SCI subjects B and K showed a velocity dependence when they were calculated over the entire ramp and hold phases of the perturbation. These results indicate that these measures might be useful in diagnosing spasticity. In all neurologically intact subjects, the torque responses for the relaxed (no muscle activation) condition were quite different from responses in which the subject applied a volitional plantarflexion bias. These responses in turn were quite different from those obtained when the soleus was electrically stimulated.

Future Plans—We have a very sophisticated set-up for measuring ankle, elbow, and knee compliance and reflex activity. We expect to gain fundamental insights into how motor reflexes are altered by spinal cord injury and how electrical muscle stimulation (EMS) interacts with these reflexes. We will measure changes as time progresses post-spinal-injury and quantify effects of medications and of EMS. We also should be able to explain observed differences in joint compliance and reflex measures between volitional and EMS-induced contractions. We hope that the ultimate outcome of this research will be techniques for better management of spasticity and spasms that accompany spinal cord

injury and for the practical application of functional electrical stimulation through a detailed knowledge of its interactions with the underlying residual neuronal substrates.

Recent Publications Resulting from This Research

A Comparison in Neurologically Intact and Spinal Cord Injured of Ankle Joint Compliance and Reflex Activity to Angular Perturbations Using Volitional and Electrically Stimulated Biases. Flaherty B, et al., in Society for Neuroscience Abstracts (#544.10), 1990.

Biomechanical Responses to Ankle Perturbations During Electrical Stimulation of Muscle. Robinson CJ, et al., in Advances in External Control of Human Extremities X, 145-158, Dejan Popovic (Ed.). Belgrade: Yugoslav Committee for Electronics and Automation, 1990.

Reflex Responses to Ankle Perturbations during Electrical Stimulation of Muscle. Robinson CJ, et al., presented at the Rocky Mountain Bioengineering Conference, Denver, CO, 1990.

Responses to Ankle Perturbations During Electrical Stimulation of Muscle: Interaction Between Ankle Compliance and Timing of Stimulation. Robinson CJ, et al., in Proceedings of the IEEE Engineering in Medicine and Biology Society 12th Annual International Conference, 2190-2191, 1990.

Design and Characterization of Knee Joint Compliance Testing Device. Fehr L, et al., in Proceedings of the IEEE Engineering in Medicine and Biology Society 13th Annual International Conference, 1991.

Determining Appropriate Models for Muscle Control Using Surface Electrical Stimulation of Soleus Muscle in Individuals with Spinal Cord Injury. Robinson CJ, et al., presented at the World Congress on Medical Physics and Biomedical Engineering, Kyoto, Japan, 1991.

Modulation of Stretch Reflexes by Surface Electrical Stimulation in Spinal Cord Injured and Neurologically Intact Subjects. Flaherty B, Robinson CJ, Agarwal GC, in Society for Neuroscience Abstracts, 1991.

The Effects of Sub-maximal Surface Electrical Stimulation on Stretch Reflexes in Neurologically Intact and Spinal Cord Injured Subjects. Flaherty B, Robinson CJ, Agarwal GC, in Proceedings of the IEEE Engineering in Medicine and Biology Society 13th Annual International Conference, 1991.

[421] Pilot Study on the Postural Effects of Intra-Abdominal Pressure

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Sponsor: VA Rehabilitation Research and Development Service (Project #A90-54AP)

Purpose—The lumbar spine is often injured with twisting and lifting activities. This predisposition to injury with torsional loads has been attributed to intrinsic structural properties of the lumbar spine. We propose that a decrease in the ability to generate sufficient intra-abdominal pressure, while the trunk is rotated, may be an additional contributing mechanism for this predisposition toward low back injury while twisting and lifting.

When lifting heavy loads in a flexed position, trunk musculature contraction converts the abdominal and thoracic cavities into nearly rigid-walled cylinders which are capable of transmitting part of the load away from the spine. EMG studies have shown that the internal and external oblique abdominal muscles are the most active of the abdominal muscles during Valsalva's maneuver. It is therefore felt that these oblique muscles have primary responsibility in the generation of increased intra-abdominal pressure with heavy lifting. Muscle fibers can produce the greatest tension when near their resting length. Strength of muscle contraction drops off quickly as muscle is shortened or lengthened in

relation to this resting length. Therefore, fibers of the oblique abdominal muscles are at a biomechanical disadvantage when the trunk is rotated, because they are shortened on the side rotated toward and lengthened on the side being rotated away from. Maximal intra-abdominal pressure during Valsalva's maneuver would therefore be expected to be decreased in a position of trunk rotation. This would lead to a decrease in the protection offered to the spine by the rigid-walled cylinder of the abdomen during heavy lifting in a position of trunk rotation.

This theory was tested in a pilot study on one healthy subject. Maximal intra-abdominal pressure was monitored during Valsalva's maneuver while the trunk was in a position of flexion versus combined flexion rotation. Twenty-five percent greater maximal intra-abdominal pressure was generated in the flexed position than in the flexed rotated position. A larger study is now proposed to establish the statistical significance of this observation.

Methodology—Intra-abdominal pressure is moni-

tored by use of a pressure sensitive radiotelemetry capsule in the stomach. Volunteers are encouraged to generate maximum intra-abdominal pressure by Valsalva's maneuver while standing in a neutral position, standing straight up while rotated to one side, standing while forward flexed, standing while

forward flexed and rotated to one side, and finally, while sitting. Consistency of maximum effort is ensured by biofeedback of the pressure readings to the volunteer and by surface EMG recording over the oblique abdominal muscles.

[422] The Corticospinal System

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Sponsor: VA Rehabilitation Research and Development Service (Project #B389-2RA)

Purpose—The purpose of our studies is to identify corticospinal systems that may be important in the recovery of motor function following spinal cord injuries or cortical damage. Our current studies focus on the corticospinal projections from the primary motor cortex and the premotor areas in the frontal lobe. Classically, the premotor cortex has been viewed as functionally distinct from the primary motor cortex and as a center for the integration of complex skilled movements. Premotor cortex was thought to participate in the generation and control of distal movement only through its projections to the primary motor cortex (area 4). On the other hand, a remarkable recovery of motor function can follow lesions of the primary motor cortex. Several studies have suggested that this recovery may depend on the integrity of output pathways from the premotor cortex. We have proposed that premotor cortex actually consists of multiple spatially separate premotor areas. Each of these premotor areas projects directly to the primary motor cortex. In addition, in this project period we have demonstrated that each premotor area projects directly to the spinal cord and, as a result, each has an output pathway that is independent of the primary motor cortex. Our present studies focus on defining the somatotopic organization of corticospinal projections from the premotor areas.

Methodology—We have used retrograde transport of multiple fluorescent tracers to examine the topographic organization of corticospinal projections in macaques. In some experiments we have compared the origin of corticospinal projections to forelimb and hindlimb regions of spinal cord (lower

cervical and lower lumbosacral segments). In others we have compared the origin of projections to presumed proximal and distal forelimb segments of spinal cord (upper cervical and lower cervical segments).

Results—Our results provide new insights into the pattern of body representation in the premotor areas of the frontal lobe. We have found that each of the six premotor areas has a distinct projection to cervical and lumbar segments of the spinal cord. Furthermore, the origins of these projections defines spatially separate forelimb and hindlimb representations in each premotor area. Five of the six premotor areas also have distinct projections to upper and lower segments of cervical cord. This observation suggests that there is a hand, as well as a shoulder representation in five of the premotor areas. Thus, the output from the premotor areas is likely to be involved in the generation and control of movements of both distal and proximal body parts.

We also have made a surprising observation on the pattern of forelimb representation in the primary motor cortex itself. Two separate high-density bands of labeled neurons were found in the primary motor cortex after tracer injections into lower cervical segments of the spinal cord. One of the bands was located at the center of the region of area 4, which is classically defined as the "hand area." The second band was located in the most medial portion of the "arm" representation in area 4. Approximately equal numbers of corticospinal neurons were found in each band. These results suggest that the primary motor cortex contains at least two hand representations. This suggestion needs to be tested with

physiological methods. However, taken together, our findings on the primary motor cortex and the premotor areas indicate that there are multiple regions in the frontal lobe that could potentially contribute to the recovery of proximal and distal movement following localized lesions of the spinal cord or cortex.

Recent Publications Resulting from This Research

Premotor Areas: Corticospinal Projections to Upper and Lower

Cervical Spinal Cord. He SQ, Dum RP, Strick PL, Soc Neurosci Abstr 16:241, 1990.

Premotor Areas: Nodal Points for Parallel Efferent Systems Involved in the Central Control of Movement. Dum RP, Strick PL, in Motor Control: Concepts and Issues, D.R. Humphrey, H-J. Freund (Eds.). London: Wiley, 1990:383-397.

Termination of Corticospinal Efferents within the Cervical Cord of New World Primates. Bortoff GA, Strick PL, Soc Neurosci Abstr 16:729, 1990.

The Origin of Corticospinal Projections from the Premotor Areas in the Frontal Lobe. Dum RP, Strick PL, J Neurosci 11:667-689, 1991.

[423] Immune Responses to Pneumococcal Vaccine in Spinal Cord Injury

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Sponsor: National Institute on Disability and Rehabilitation Research

Purpose—Pulmonary complications, with pneumonia being the most frequent, are a major cause of both morbidity and mortality in persons with spinal cord injury (SCI). Both bacterial and viral immunizations have been recommended to prevent infectious pulmonary complications in patients with neuromuscular disorders producing mechanical dysfunction of the respiratory system. Although patients with SCI, particularly quadriplegics and high paraplegics, have been shown to be at increased risk for the development of serious pulmonary complications, including pneumonia, we are unaware of any studies documenting the efficacy of either bacterial or viral immunizations to reduce the incidence of pulmonary complications in the population with SCI.

The objectives of this study are to document changes in laboratory values of patients vaccinated with pneumococcal vaccine at varying intervals after SCI; compare the incidence of pulmonary complications in unimmunized patients with SCI with the incidence in a series of patients with SCI vaccinated at varying times following injury; and, define the optimal time after SCI for pneumococcal vaccination.

Methodology—This study will entail random assignment of SCI patients into one of six groups following their entry into the University of Alabama at Birmingham (UAB) Hospital care system. Groups

1 and 2 will receive pneumococcal vaccine or placebo, respectively, within 72 hours (+/- 24 hours) of injury. Groups 3 and 4 will receive the vaccine or placebo at 17 days (+/- 24 hours) of injury. Groups 5 and 6 will receive the vaccine or placebo at 4-6 months postinjury. The groups for which a patient is eligible to be randomized as a subject (to receive vaccine) or control (to receive placebo) will be determined according to the time at which the patient is admitted to the UAB Hospital or Spain Rehabilitation Center.

Randomization will be performed so that approximately equal numbers of persons will be enrolled into each of the three experimental groups and three control groups, and approximately equal numbers of quadriplegics and paraplegics will be included in each study group and control group.

This study will be blinded to the patient and their primary care physician. Only the data coordinator and the principal investigator will know whether a patient received vaccine or placebo. The code will be broken if a medical emergency warrants it. Following enrollment, blood samples will be collected on four separate occasions: the first at the time of vaccination or administration of placebo, the second 1 month later, the third 2 months later, and the fourth at 1 year following enrollment.

Laboratory tests to be performed at each blood sampling interval include: antipneumococcal antibody titers to four major serotypes, quantitative

immunoglobulin, complete blood count with differential leukocyte count, liver profile, total serum protein and albumin. Subjects and controls will be monitored during their initial hospitalization for the occurrence of respiratory or other systemic complications of pneumococcal disease. Appropriate mi-

crobiological and/or immunological diagnostic procedures will be implemented whenever possible to determine whether or not such complications are indeed due to infection with *Streptococcus pneumoniae*.

[424] A Double-Blind, Randomized, Prospective Pilot Study to Assess the Safety, Efficacy, and Practicality of Low Molecular Weight Heparin and Pneumatic Compression Sleeves as Prophylaxis for Deep Vein Thrombosis in Acute Spinal Injured Patients

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Sponsor: *Paralyzed Veterans of America, Spinal Cord Research Foundation*

Purpose—Blood clots in the lungs (pulmonary embolus or PE) remain one of the leading causes of death in acute spinal injured patients. These blood clots originate from the deep veins of the lower extremities. Currently, three methods to prevent these lower extremity blood clots (deep vein thrombosis or DVT) have been shown to be effective. Each of the modalities use a form of mechanical compression to improve the return of blood from the lower extremities and a blood thinner (aspirin/dipyridamole or heparin) to reduce clotting. The major problem with these methods is their interference in the rehabilitation program, and each therapy used individually is not effective. In the first 2 weeks following injury, the combination modality can be applied easily, but in the third and fourth weeks the mechanical devices are frequently discontinued due to the active nature of the rehabilitation program. This leaves the single modality of blood thinners which have not been shown to be effective as sole agents. The goal of this study will be to optimize a method of preventing blood clots in the legs of acute spinal injured patients in the first 4 weeks following injury.

Methodology—The modalities chosen are compression sleeves (external pneumatic compression), because they can be easily applied and are universally available, plus a new type of blood thinner (low molecular weight heparin or LMWH-ORG-10172) that is better-absorbed, longer acting, has less risk for bleeding, and is more effective in preventing

blood clots. Fifty patients (25 per year over 2 years) who meet the entry criteria will be randomized in an ongoing fashion to receive one of two treatments: compression boots plus new heparin (750 units twice per day), or compression boots plus new heparin (1,250 units once per day with the second dose being an inactive substance). The compression boots will be discontinued at the end of the second week following injury when the active rehabilitation program begins. The new heparin will continue in each group for the remainder of the third and fourth weeks.

All patients will have entrance laboratory testing to evaluate their clotting status. Patients will have daily surveillance for the development of blood clots in their legs by using a test called the 125-1 fibrinogen scan. This test detects forming blood clots by a protein that attaches itself to the clot and is detected by scanning the leg's surface. If the patients enter the hospital more than 72 hours, but less than 7 days after their injury, they will have another test called impedance plethysmography. This test uses blood pressure cuffs to measure impedance to blood flow. The combination of impedance plethysmography and 125-1 fibrinogen scanning is very good at detecting any blood clots that may have been formed before the patient came to the center. The objectives of these two methods is to assess the effectiveness of the treatments to prevent blood clots. The patients will be examined daily to assess the practicality, tolerability, and safety of the therapy.

[425] Occupational Therapy Graduate Traineeship in Spinal Cord Injury**William C. Mann, OTR, PhD**

Occupational Therapy Department, State University of New York at Buffalo, Buffalo, NY 14214

Sponsor: Paralyzed Veterans of America

Purpose—There is presently a critical shortage of occupational therapy faculty. Educational programs across the country cannot fill the number of vacant positions. At the same time, there is an increased need for more occupational therapists in clinical positions, and as a result more entry-level educational programs are being established. These new programs further exacerbate the problem of short supply of qualified faculty. Occupational therapy is becoming increasingly specialized, with practices ranging from the mental health setting to schools, hospitals, and rehabilitation centers. Clinical specialists are needed who are knowledgeable about the newest methods of patient care and evaluation, and who have a firm background in the biological and behavioral sciences.

With the shortage of occupational therapists, starting salaries for entry-level (primarily baccalau-

reate degree) therapists are very favorable upon graduation. Thoughts of graduate school compete with the reality of a relatively high-paying position and the possibility of paying off student loans accumulated in the past 4 years. All these factors render student recruitment for graduate programs in occupational therapy very difficult. Without financial support for graduate studies, occupational therapists generally do not consider graduate school, unless they are in one of the few locations where there is an occupational therapy graduate program and they can study part-time.

Through this project, one post-professional occupational therapy graduate student will receive support to concentrate his/her studies on spinal cord injury. This student will be working toward an MS degree in occupational therapy in the existing physical disabilities concentration area.

[426] Rehabilitation Technology Intern Training Project**Martin W. Ferguson-Pell, PhD**

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Sponsor: Paralyzed Veterans of America

Purpose—Recent advances in technology have made techniques available to persons with disabilities that will allow them to function with increased independence and gain more control over themselves and their environments. Persons with severe disabilities have the potential to benefit the most from technology, but because they are commonly given custodial care only, they are unlikely to receive such services. The rapid growth in rehabilitation technology (RT), coupled with recent amendments to the Federal Rehabilitation Act, has left a serious shortage of skilled, knowledgeable, clinical service providers.

Rehabilitation technologist is a term used for all rehabilitation professionals who have specialized training in RT. The use of the same job title for staff members from different professional backgrounds is symbolic of the conviction that RT

service delivery requires an unusually high level of interdisciplinary cooperation. The purpose of this proposal is to create an interdisciplinary Rehabilitation Technology Intern (RTI) team of professionals to work with a small number of persons with profound functional limitations. The primary outcome of the project is to train the interns in rehabilitation technology. Another outcome of this project is to increase the independence of the clients involved in the RTI training program.

Methodology—A physician, an engineer, and three rehabilitation clinicians will work together in a unique and challenging internship that provides an intensive experience in the development and application of rehabilitation technology, and also provides timely, coordinated, and intensive RT services to

clients who would be unlikely to receive them otherwise. An extensive evaluation of the program will be undertaken and disseminated. The evaluation will include structured interviews with the participants. Members of the RTI team will be interviewed regarding their attitudes toward RT, and toward the other disciplines represented on the team. They will be asked to assess the quality and quantity of knowledge gained. Clients who participate and their

caretakers will be questioned about changes in the client's functional independence and self-concept as a result of the program. A critical final outcome of the project is the dissemination of the model to other centers that now train rehabilitation technologists, or plan to do so, via publications in journals, presentations at conferences, and a comprehensive printed report.

[427] Intrathecal Baclofen for Intractable Spinal Spasticity: A Double-Blind Crossover Comparison with Placebo Followed by Chronic Daily Intrathecal Bolus Injections

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Sponsor: *Physician's Services Incorporated Foundation; CIBA-GEIGY Canada, Ltd.*

Purpose—Many subjects with severe spasticity have been implanted with drug-delivery systems for chronic intrathecal baclofen (LIORESAL) administration because of the dramatic reduction in muscle tone that can be attained without the dose-limiting side effects of oral therapy. However, few studies were designed to specifically measure the magnitude of the placebo effect of intrathecal therapy as well as the baclofen effect.

Therefore, we first conduct a preliminary trial of intrathecal baclofen on subjects with severe spasticity, using a double-blind crossover paradigm with baclofen and placebo saline bolus injections in order to measure the magnitude of the baclofen and the placebo effects on muscle tone and strength, overall motor function, urodynamic parameters and a health utility index, before we recommend chronic intrathecal baclofen therapy.

Progress/Methodology—Six subjects have been studied so far. *Phase 1—Trial injections, dose finding, crossover paradigm.* We start with a dose of 10 micrograms through a percutaneous lumbar subarachnoid catheter, followed by daily incremental increases of 5-10 micrograms/day until a reproducible spasmolytic effect is observed during clinical testing. All subjects have responded to doses of only 10-30 micrograms which are much smaller doses than those reported by others. Responders are then implanted with a subcutaneous catheter access port (CAP) for further daily bolus injections at a dose

titrated to reduce spasms and tone without producing disabling weakness. The dose for our subjects varied from 22.5 to 125 $\mu\text{gm}/24$ hrs initially and bore no relationship to the etiology or severity of their spasticity.

Subjects then complete a double-blind crossover paradigm of two treatments of intrathecal baclofen and two of placebo saline in random order, with a 48-hour washout between treatments and clinical testing during each treatment. Parameters for significant clinical improvement were developed by consensus at the beginning of the study.

The baclofen treatment scores for the group and each individual subject have improved in all subtests except those pertaining to upper limb function in contrast with placebo treatment scores which also improved from baseline scores, but to a much lesser degree. This baclofen treatment effect has been clinically significant for a reduction in trunk and leg spasms, lower-limb muscle tone, lower-limb reflexes, disability scores, and for a greater passive range of motion in the legs.

Phase 2—Daily intrathecal bolus injections at a fixed dose \times 30d. When preliminary analysis supports a baclofen treatment effect, subjects continue daily intrathecal baclofen bolus injections at their individual dose for 30 consecutive days by self-administration or from a caregiver and they are tested again to determine if the initial baclofen treatment effect can be maintained and to measure a health utility index.

There has been a rise in the disability scores from the initial baclofen treatment scores, but the improvements in tone and spasms have been maintained in all subjects. Two subjects demonstrated some additional weakness in their legs after 30 days of bolus injections at a fixed dose. Urodynamic parameters did not change during Phase 1 to either treatment, but improved after 30 days in two subjects, one of whom was able to convert from an indwelling Foley catheter to intermittent catheterization.

Phase 3—Chronic daily bolus injections with titration of dose to maintain satisfactory spasmolysis. When it is apparent that benefit continues after 30 consecutive days of bolus injections at a fixed dose, subjects continue intrathecal bolus injections, but their doses are now titrated to maintain optimum spasmolysis for each individual subject.

This has resulted in gradual dose escalations up to 350% from the original therapeutic dose over a 12-month interval in five out of six subjects.

Throughout the phase of chronic daily bolus injections a careful record of direct and indirect costs of treatment is maintained for future comparison against chronic intrathecal baclofen infusion using implanted infusion pumps. To date, three of the six subjects have been implanted with such infusion pumps and are now receiving their intrathecal baclofen by infusion with continuing benefit.

Implications—Future calculations of the cost utility of these two methods of intrathecal baclofen treatment are expected to impact on the utility of this approach to treating intractable spasticity.

B. Treatment and Rehabilitation

[428] Development and Testing of New Spinal Implant Systems

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Sponsor: VA Rehabilitation Research and Development Service (Project #B365-2R)

Purpose—The overall purpose of this project has been to more completely define the dynamic biomechanical properties of retrieved laboratory animal spines; to conduct cyclic testing on surgical implant systems and implant and spine constructs *in vitro*; and to evaluate new implant systems *in vivo* in primates for functional safety and efficacy. The data were then utilized to design, test, and apply new devices useful for surgical reconstructions and rehabilitation within veteran patient populations.

Progress/Methodology—Laboratory analyses were expanded to include several biomechanical models and test systems on the MTS Bionix 858 dynamic testing system. Dynamic fatigue compression, torsion, and combined compression-torsion testing were applied to swine and primate spines. A new

three-dimensional (3-D) TV and computer-based methodology was completed and calibrated for motion analyses of whole spines and adjacent vertebral bodies. The redesigned anterior spinal implant device was placed in four baboons for *in vivo* functional evaluations at 6 months. The surgical placement, rehabilitation, function, and necropsy-implant recovery were completed without difficulties or unanticipated results. The retrieved spines with the implants in-place were tested biomechanically (axial and torsional loading with 3-D motion analyses) for force and motion-related properties. Subsequently, the spine and implant segments were fixed in formalin and subjected to multiplanar nondecalcified thin sectionary. Laboratory analyses of the fatigue properties of the implants alone are now being completed.

Future Plans—The project objectives were completed in February, 1992. This included all phases of the *in vitro* and *in vivo* investigations. The plans are

to fully evaluate the data developed during the 3-year program, compile a comprehensive final report, and publish specific studies as applicable.

[429] Management of the Musculoskeletal Complications of Spinal Cord Injury

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Sponsor: VA Rehabilitation Research and Development Service (Project #B576-RA)

Purpose—This project is designed to develop and apply newly discovered, bone cell-specific serum markers to clinical studies of musculoskeletal assessment in patients with trauma and illness involving the spinal cord. The methods to be used involve new immunoassay procedures with increased sensitivity and defined specificity for classical skeletal markers such as bone alkaline phosphatase (BAP) and bone acid phosphatase (BAP), and new skeletal markers such as bone Gla protein, (BGP, osteocalcin) and its derived peptides. It is our hypothesis that these procedures will assist in the design and evaluation of treatment regimens for patients with spinal cord injury and disease. We are focusing on the development of validation of these serum markers and are now anticipating clinical studies.

Progress/Methodology—A panel of monoclonal antibodies to human BGP peptides that span the linear sequence of the molecule, specifically BGP 1-12 (N), BGP 15-30 (M), and BGP 38-49 (C) has been developed. These antibodies were evaluated in various combinations of two-site formats in studies of serum BGP concentrations. For clinical studies, the two most sensitive antibody pairs for the intact molecule (N-C) along with a polyclonal RIA based on BGP-C were selected from a panel of antibodies. For the two-site format, two N-terminal antibodies, 029 and 052, were adsorbed to polystyrene beads and a C-terminal antibody, 663, was radioiodinated. The following BGP serum concentrations (pg/ml, mean \pm SE) were measured with the respective assays: for the 029-663 assay, normal subjects, 7 ± 3 , renal failure, 25 ± 8 , Paget's disease, 12 ± 4 ; for the 052-663 assay, 22 ± 4 , 44 ± 12 , 31 ± 7 ; for the polyclonal assay, 2 ± 0.2 , 12 ± 2 , 5 ± 1 . The two intact (N-C) assays were significantly ($p < 0.01$)

correlated ($r = 0.94$), but there was greater than a two-fold difference in their serum values against the same standard. The polyclonal assay significantly correlated with each ($r = 0.83$, 0.77) of the intact assays, but it too, gave different serum values for BGP. These studies demonstrate the immunochemical heterogeneity of circulating BGP.

A comparison was made of a new immunoassay that is specific for BAP to measurements of total alkaline phosphatase (TAP) and BGP in Paget's disease. In our studies, we demonstrated that BAP was increased in the serum of patients with Paget's disease. Comparisons with the other measurements revealed that BAP correlated better with total AP ($r = 0.92$) than with BGP ($r = 0.51$); the lowest correlation occurred between BGP and total AP ($r = 0.26$). These studies indicate that BAP assesses different aspects of bone cell function than BGP in Paget's disease. This discordance also exists between BGP and total serum AP activity. BAP measurements by immunoassay offer a novel method of assessing skeletal status. Thus, the information that measurement of different bone-specific proteins provides should be separately useful in assessing the skeleton in patients with spinal cord injury and disease.

Preliminary Results/Implications—The second year of this project has resulted in significant advances in all stages of our proposed research. The above-described progress will support our goal of developing methods that will ultimately assist in the clinical management of patients with spinal cord disease and injury.

Recent Publications Resulting from This Research

A Two-Site Immunoradiometric Assay Specific for Human Bone Alkaline Phosphatase Correlates with Other Indices of

Osteoblast Function. Deftos LJ, Weisman MW, Hill CS, J Bone Min Res 55:A642, 1990.
Bone Alkaline Phosphatase in Paget's Disease. Deftos LJ,

Wolfert RL, Hill CS, Horm Metab Res (in press).
Bone Protein and Peptide Assays in the Diagnosis and Management of Skeletal Disease. Deftos LJ, Clin Chem (in press).

[430] Compression and Ischemia As It Affects Spinal Cord Injury

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Sponsor: VA Rehabilitation Research and Development Service (Project #B535-RA)

Purpose—The purpose of this project is to gain increased knowledge concerning the underlying causes of injuries to the spinal cord and spinal nerve roots.

Methodology—Pre-op medication was given to mini-pigs weighing between 35-45 kg. The animals were then intubated and ventilated. A midline neck incision was made, and the left carotid artery and internal jugular vein were cannulated for continuous monitoring of mean arterial blood pressure and to act as an IV infusion line. The right internal jugular vein was cannulated in the hypotensive and hypertensive models for infusion of the appropriate drugs. Animals were then turned prone, positioned so the abdomen was free from compression. A low posterior midline was made above the tail. A two-level sacrococcygeal laminectomy was performed under magnification, exposing the spinal nerves, and hemostasis was obtained. A pneumatic compression device was applied to the exposed spinal nerves. Stimulating and recording electrodes were placed proximal and distal to the compression device. CMNAP and CNAP data were collected as a function of compression of the nerves at various compression pressures. The duration of compression with hypotension and compression with hypertension were compared with normotension with compression, studying neural dysfunction at a fixed compression. At the termination of the experiment, the pigs were sacrificed and the compressed spinal nerves harvested for histology.

Results—Normotensive model: CMNAP and CNAP amplitude reductions with 100 and 200 mmHg of compression CNAP being more sensitive to pressure and demonstrated a significant decrease in recovery ability.

Four-hour duration model: CMNAP and CNAP amplitudes decreased more than the normotensive (2-hour duration) model. At 100 mmHg compression, conduction decreased to 20% of baseline and recovery was delayed. At 200 mmHg compression, there was a complete block of conduction with no recovery observed.

The present studies demonstrated that higher compression pressures induced increasing conduction deficit, which may be related to larger mechanical deformation of the nerve tissues. More severe neurophysiologic deficits were produced by longer spinal nerve root compression.

Hypotension model: At 50 mmHg compression, CMNAP and CNAP amplitudes decreased moderately during compression and recovered to 20% of baseline. No changes in conduction were seen in the normotensive model at this level. At 100 mmHg compression, the CNAP amplitude fell to 23% and showed minimal recovery. Amplitude recovery was slower and less complete in the hypotensive group than in the normotensive group at this level. At 200 mmHg compression, conduction loss was nearly complete during compression and showed no recovery. In the normotensive animals, amplitudes showed moderate recovery.

This study demonstrates an independent effect of hypotension on nerve roots undergoing acute graded compression. Compressive injury represents a combination of ischemic and direct mechanical damage.

Hypotension with normotension recovery model: At 50 mmHg compression, the CMNAP and CNAP amplitudes return to baseline. At 100 mmHg compression, both the CMNAP and CNAP amplitudes, during recovery, improved an additional 50% in conduction compared with the hypotension recovery model.

This study demonstrated a significant improvement in nerve root recovery with normotensive recovery conditions following a combined hypotensive and compressive nerve root insult.

Hypertension model: In progress.

Recent Publications Resulting from This Research

Nerve Roots of the Cauda Equina: The Effect of Hypotension and Acute Graded Compression on Function. Garfin SR, et al., *J Bone Joint Surg* 72-A(8):1185-1192, 1990.

The Effect of Hypotension and Acute Graded Compression on Cauda Equina Nerve Root Function (Abstract). Garfin SR, et al., American Spinal Injury Association, Orlando, FL, 35, 1990.

The Effect of Hypotension and Acute Graded Compression on Cauda Equina Nerve Root Function (Abstract). Garfin SR, et

al., International Society for the Study of the Lumbar Spine, Boston, 23, 1990.

The Effect of Hypotension and Acute Graded Compression on Cauda Equina Nerve Root Function (Abstract). Garfin SR, et al., North American Spine Society, Monterey, CA, 43, 1990.

Effects of Acute Graded Compression on Spinal Nerve Root Function and Structure. An Experimental Study of the Pig Cauda Equina. Rydevik BL, et al., *Spine* 16(5):487-493, 1991.

The Effect of Hypotension and Acute Graded Compression on Cauda Equina Nerve Root Function (Abstract). Garfin SR, et al., Federation of Spine Associations Sixth Annual Meeting, Anaheim, CA, 1991.

The Effects of Hypotension on Nerve Root Recovery Following Acute Graded Compression (Abstract). Carlson GD, et al., Transactions of the 37th Annual Meeting, Orthopaedic Research Society, Anaheim, CA, Vol. 16, Sec. 2, 685, 1991.

Effects of Magnitude and Duration of Compression on Spinal Nerve Root Conduction. Pedowitz RA, et al., *Spine* (in press).

[431] Feasibility of Chronic Recordings from Motor Cortex for Prosthesis Control: A Pilot Study

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Sponsor: VA Rehabilitation Research and Development Service (Project #A90-209AP)

Purpose—Fundamental studies are planned to determine the feasibility of obtaining control signals from the motor cortex suitable for controlling a neural prosthesis. Recent advances in the field of functional neuromuscular stimulation (FNS) brought these systems to the point of clinical implementation for restoring movement to paralyzed muscles in both the upper and lower extremities. FNS systems have demonstrated promising potential for increasing the independence of the disabled. The technology exists to expand FNS systems to include more degrees of freedom and thus more sophisticated limb control. A major bottleneck to further development of FNS, as well as its application to patients with more severe injuries, has been a lack of suitable command sites. Control signals currently employed are limited in the information they can transmit and interfere with other ongoing tasks. Obtaining control signals directly from the central nervous system (CNS) would significantly expand the quality and number of available command sites, improving the potential of a patient to use more sophisticated FNS systems. Since their origin would be above all levels of spinal cord injury, such control signals would allow use of

these systems to be extended to the more severely disabled.

The CNS, in particular the motor cortex, is recognized as a natural source of signals directly related to limb and body movements. Due to its unique anatomy and physiology, the motor cortex may offer a sufficient degree of controllability and independence between simultaneously active cells to provide a significant improvement over currently employed control signals. Tapping these signals as a command source for driving a neural prosthesis seems the ideal solution to providing a large number of independent control signals. To achieve this, long-term connections must be made with delicate neural tissue. Recently developed microelectrodes show promise of establishing such connections.

Methodology—This pilot study will develop the use of multisite microprobes for obtaining chronic single-unit recordings from the CNS. Microprobes are tiny, thin film electrode arrays which were used previously for recording single units in acute preparations, further developed, and which now appear to have solved a number of problems typically associ-

ated with chronic implantation including electrode stability, lead wire strength versus flexibility, and connection continuity. Microelectrodes will be implanted into the motor cortex of cats, a site with a well documented anatomical structure and easily accessed surgically. We will measure how long an individual unit may be recorded as well as how long each recording site remains viable. Recording quality, electrode movement, connector and lead continuity, and possible tissue reaction will be assessed. Using correlation techniques, the spacing between electrodes and between adjacent recording sites most appropriate to obtain independent signals will be determined. Performance of the multisite microprobes will be compared to hatpin electrodes

which have been used previously for long-term recording of single units.

Establishing long-term connections with the CNS will contribute substantially to the long-term goal of understanding how control signals in the CNS are generated and how these signals might be used to control a neural prosthesis. The results obtained from this feasibility study will be used to select the best electrode array design and implant configuration that will provide multiple channels of stable information. Multiple independent channels would expand the degrees of freedom of a neural prosthesis which could be controlled actively, increasing the functionality and sophistication of these systems.

[432] Interactive Videodisk Training for Self-Care Skills

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Sponsor: VA Rehabilitation Research and Development Service (Project #B451-RA)

Purpose—The success of traditional methods of healthcare education may be influenced by factors such as the student's psychosocial, economic, or educational status; the extent of involvement by healthcare professionals; or the instructional material or methods. Although some of these factors can be controlled and improved, others cannot. Accordingly, healthcare professionals who may have little time for patient education are faced with the problem of instructing people with diverse socioeconomic backgrounds, attitudes, and skills.

There is a growing body of evidence that interactive multimedia instruction may help resolve this problem. With interactive multimedia, instructional designers may incorporate sound, graphics, text, and video into their material. This not only makes the material more interesting but also increases its potential for conveying information.

Progress/Results—We have experimented with a variety of interactive instructional materials over the term of this project. Our first efforts were directed primarily at developing software to make it easier for healthcare professionals to develop their own interactive training material. The result of these

efforts was a menu-driven authoring package for IBM-compatible personal computers that allows the user to create graphics, computer-generated speech, menus, and two- or four-alternative questions, and to control commercial videodisk players. It also provides the user with the ability to establish the sequence of instructional material, thus enabling him or her to create complex scenarios with feedback to the student. This package is now available as public-domain shareware.

Interactive materials were developed with this package and tested using patients at Hines VA Hospital. The results were mixed due to the difficulty of developing instructional material that interested patients and satisfied the needs of healthcare professionals in terms of conveying appropriate information. In fact, it was our experience that developing the content of instructional interactive media was far more difficult than developing the instructional program. Most of the difficulties arise from differences in opinions on content and the extent to which content must be individualized because of large differences in students' physical abilities.

Because of this problem, we have focused our

most recent efforts on developing instructional programs on subjects that are relatively independent of physical abilities. For example, our latest product is an interactive, multimedia package on maintaining and repairing manual wheelchairs. This program has been well accepted by people with disabilities,

manufacturers, and healthcare professionals. Our latest efforts have involved transporting this program to the Macintosh™ to take full advantage of new developments such as HyperCard™ and Quicktime™.

[433] Urinary Bladder Stimulation Following Spinal Cord Injury

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Sponsor: VA Rehabilitation Research and Development Service (Project #B441-2RA)

Purpose—After spinal cord injury, control of bladder function is usually lost. The goal of this project is to learn more about the mechanism of bladder dysfunction following spinal trauma and to use this knowledge to develop ways to manage urinary problems following injury. Methods of stimulating sacral nerves and the bladder directly are under investigation. We have developed an instrumented cat model for chronic recording in the unrestrained animal. This instrumentation will allow us to compare bladder function and responses to stimulation both before and after spinal cord injury.

Methodology—Instrumentation was conducted under anesthesia during surgery in the intact cat. We implanted eight electrodes for direct bladder wall stimulation: each is a "woven eye" electrode constructed of 316LVM stainless steel wire stripped of insulation and woven into a 0.5 cm circle to suture to the bladder wall. One electrode was also inserted into the sacral canal for sacral nerve stimulation. Bladder and abdominal catheters were inserted along with electrodes in the legs and pelvic floor to record muscle activity. A second surgery was conducted under anesthesia for complete spinalization (T-1), and stimulation was evaluated after SCI.

Progress/Preliminary Results—After recovery from surgery in the intact and freely moving cat, the bladder was filled (cystometry) and micturition was observed. The micturition volume was 20 to 30 ml at a bladder pressure of 40 to 70 cm H₂O. The pelvic floor electrical activity showed an increased activity

during filling and decreased activity during micturition. However, phasic pelvic floor activity was present during voiding. Electrical stimulation induced bladder contractions and voiding in this intact animal. Electrical stimulation applied for 3 sec at 40 pps and 15 to 25 ma induced bladder contractions. The stimulation was usually followed by the cat assuming a normal voiding stance and voiding. Electrodes at the base of the bladder were more effective than electrodes on the dome. Preliminary observations in the cat after spinal cord injury indicate that similar stimulating parameters are needed after SCI as before SCI. We conclude that suturing electrodes close to the neural innervation along the ureter-bladder junction may help to reduce the high stimulating currents needed to induce micturition.

Future Plans—We plan to evaluate a multichannel implantable simulator for micturition control, bladder stimulation for voiding, and pelvic floor stimulation for preventing incontinence. Such systems have been or are being developed at Case Western University and Rancho Rehabilitation Engineering Center.

Recent Publications Resulting from This Research

Direct Bladder Stimulation for Micturition Control. Walter JS, et al., in Proceedings of the 37th Annual Conference of the American Paraplegia Society, 36, 1991.
Evaluation of a 316LVM "Woven Eye" Electrode for Direct Bladder Stimulation. Walter JS, et al., IEEE Trans Biomed Eng (in press).

[434] Effect of Exercise on Upper Extremity Recovery Following Quadriplegia

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Sponsor: VA Rehabilitation Research and Development Service (Project #B320-2RA)

Purpose—Acute quadriplegia is commonly followed by some recovery of function in one to two spinal segments at the level of the cord injury. For example, a patient with C4 quadriplegia often recovers some C5 function, allowing use of the upper extremities for operating a power wheelchair and for self-feeding. This upper extremity recovery probably results from several mechanisms including: 1) resolution of UMN weakness; 2) resolution of a transient conduction block in descending motor pathways of the spinal cord, or in lower motoneurons or roots; 3) motor axon sprouting by spared motoneurons to reinnervate denervated muscle fibers; and, 4) muscle fiber hypertrophy in spared motor units. This study attempts to distinguish the relative contributions of these various mechanisms to the recovery process and to explore the role of exercise in facilitating this recovery.

Methodology—Weak upper extremity muscles in patients with recent traumatic quadriplegia are examined using a battery of electrophysiologic tests to distinguish and quantitate the relative contributions of upper and lower motoneuron dysfunction to the weakness. One weak muscle is randomly assigned to receive standard twice-daily strengthening; the other weak muscle receives strengthening 3 times per week. Subsequently, both muscles receive standard twice-daily strengthening. The battery of electrophysiologic tests are repeated monthly to monitor the patterns of recovery and the effects of differential strengthening.

Results/Future Plans—Several distinct types of weakness have been distinguished by comparing compound muscle action potential amplitudes (M amplitudes) as a percent of normal and maximal motor-unit firing rates. Some weak muscles have

relatively spared M amplitudes but slow firing rates; others show very low M amplitudes but fast motor-unit firing rates. These findings are consistent with upper and lower motoneuron type weakness respectively. LMN-type weakness is more common in C5 than in C7-innervated muscles. UMN-type weakness in the upper extremities is more common in those with Frankel C or D spinal cord injury (i.e., motor incomplete for long tracts) than in those who are motor complete.

Current work addresses the temporal patterns of recovery and the effects of exercise on this recovery. Those muscles with relatively preserved M amplitudes show greater likelihood of achieving recovery of functional strength. Compound muscle action potential amplitude, RMS of maximal voluntary electromyographic activity, motor-unit firing rate and motor-unit action potential amplitude all tend to increase with recovery of strength, though the temporal course of these individual changes has not yet been well-characterized.

As a sidelight of this research, it was noted that two of our patients developed posttraumatic syringes; we have begun to explore the use of electrophysiologic parameters for diagnosing and monitoring such syringes. More sensitive electrophysiologic methods for monitoring posttraumatic syringes may allow earlier and more effective treatment.

Recent Publications Resulting from This Research

Electromyographic Evidence for Motor Axon Sprouting in Recovering Upper Extremities of Acute Quadriplegics. Little JW et al., J Am Para Soc 13:16, 1990.

Electrophysiologic Methods for Diagnosing and Monitoring Post-Traumatic Syringomyelia. Little JW, Stewart D, J Am Para Soc 13:7-8, 1990.

Motor Evoked Potentials Reflect Spinal Cord Function in Post-Traumatic Syringomyelia. Robinson LR, Little JW, Am J Phys Med Rehabil 69:307-310, 1990.

[435] Control of Perioperative Hemodynamic Instability in Quadriplegia

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Sponsor: VA Rehabilitation Research and Development Service (Project #B516-RA)

Purpose—Complete injury to the cervical spinal cord effectively removes all sympathetic outflow from higher centers while parasympathetic control remains largely intact. As the cardiovascular system is highly dependent upon autonomic influences, it is logical that this injury pattern might interface with the complex mechanisms involved in hemodynamic stabilization. We have previously shown that acute cervical injury in man results in a variety of cardiovascular abnormalities, including bradycardia, hypotension, tachyarrhythmias, and cardiac arrest. Fortunately, these autonomic disturbances resolve spontaneously 2 to 6 weeks after injury via an unknown mechanism. Although this adaptive response is obviously beneficial to the rehabilitative goals of the quadriplegic patient, the chronic stage of cervical SCI is marked by its own set of cardiovascular abnormalities.

Chief among these is autonomic dysreflexia. This condition, found in more than 85% of quadriplegics, is characterized by transient episodes of profound hypertension, diaphoresis, piloerection, headache, seizures, and even death. To date, the mechanism of this apparent mass sympathetic reflex has not been established, and no satisfactory treatment has been discovered.

During rehabilitation, patients at risk learn proper techniques of bowel and bladder manipulation to minimize the likelihood of triggering a dysreflexic episode. However, the barrage of afferent nervous activity that accompanies a surgery represents a potent stimulus of dysreflexia. This phenomenon, combined with baseline vasodilation and hypotension, makes intraoperative hemodynamic control in quadriplegia extremely difficult.

Indeed, systolic arterial pressure swings of over 100 mmHg are commonly encountered during surgery. Surprisingly, there have been no prospective studies published to date that well characterize the magnitude of this problem.

Methodology—There is considerable controversy as to the ideal anesthetic and pharmacologic approach to take in these individuals. Each technique tried in the past has intrinsic limitations that precludes widespread applicability. On both theoretic and empiric grounds, the transdermal administration of the α -agonist clonidine may effectively blunt both extremes of blood pressure variation during surgery when given prophylactically. Preliminary data from our laboratory strengthens this concept, and supports the need for a large-scale investigation.

We are studying this new technique of perioperative hemodynamic control via a randomized, double-blind, placebo-controlled trial. Transdermal clonidine or a matching placebo are administered to patients with chronic, complete quadriplegia undergoing surgery. Several physiologic parameters are monitored noninvasively during the procedure to assess autonomic and hemodynamic function, including arterial pressure, electrocardiographic ST segment height, tissue oxygen tension in areas below the level of injury, and sympathetic neurohormonal release. Finally, subjective sensations are quantitated in awake patients using strictly defined criteria. In addition to intraoperative assessment, blood pressure and heart rate are monitored in the immediate postoperative period using a portable measuring device.

[436] Analysis of Functional Independence Measure (FIM)

Machiel Van der Loos

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Sponsor: VA Rehabilitation Research and Development Center (Core Funds)

Purpose—The objectives of this study are to examine the long-term assessment of functional independence of disabled individuals to show progress in rehabilitation and the effect of in-clinic as well as in-society periods of retraining and re-adaptation. By assessing levels of function at periods separated by months or years, the rehabilitation community can find patterns of successful recovery and areas of increased need, either for more therapy, more technical aids, or a redistribution of effort through each person's rehabilitation.

The VA Spinal Cord Injury Center (SCIC) has compiled assessment forms on all its patients for the past 10 years. The forms, completed by occupational therapists, show the functional independence of the patients in completing 128 activities of daily living (ADLs). These forms are completed each time a patient is admitted, and thus chronicle the

person's rehabilitative progress over time.

Methodology—Over 100 patient assessment forms have been logged into a computerized database. Records were screened for quadriplegic patients (lesions C7 or higher) who had forms satisfying all of the following criteria: 1) a first assessment less than 6 months post-injury; 2) a second assessment between 6 and 12 months post-injury; and, 3) a third assessment between 1 and 3 years post-injury.

Half of the available assessment forms were retained for analysis. The first assessment is a baseline, showing the full effect of the injury. The second shows the effect of initial physical and occupational therapy, since an acute patient spends 6 to 12 months in-clinic following the injury. The third assessment shows progress while the disabled person readjusts to life in the community.

[437] Neural Prosthesis Pilot Study on Frogs

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Sponsor: VA Rehabilitation Research and Development Unit (Core Funds)

Purpose—The purpose of this study was to obtain data and expand the knowledge base for the utilization of transient magnetic field stimulation of nerve and muscle group tissue. The subject specimen for the study was the bullfrog.

Methodology—A C-shaped permendur nickel-iron core was wound with 38 turns and activated with a 400A current pulse with a characteristic frequency of 25kHz. The transient field was sufficient to induce electric fields in the neighborhood of 0.1–0.4V/m.

Progress—This induced field was just sufficient to stimulate large muscle groups. More effective stimulation was realized by using 1–3 turn gaped coils

implanted around the desired nerve or muscle group. Both the hamstring muscle and the sciatic nerve were selectively stimulated with this technique on a pithed bullfrog. Of some concern was the long-term effect such stimulation might have on the nerve (i.e., the extent of necrosis). The pilot study did not find any evidence to support this concern. The ability to stimulate the nerve selectively and repeatedly at an excitation frequency of 15 Hz (repeating the 50 μ s pulses at 15 Hz) establishes the foundation for the use of such a technique in direct nerve stimulation.

Implications—If successful, the alternative of directly stimulating nerves magnetically could offer many advantages over conventional electrical stimu-

lation. There would be no need for transcutaneous electrodes. All stimulation could be realized by external apparatus with selectivity and enhancement gained by a passive implant (either ferromagnetic, conductive, or resistive). With resistive implants, nonconducting wafers could be employed to focus

the electric current and thus the induced electric field; this stimulation would have none of the half cell reactions which plague conventional stimulation, since the electric field results from eddy currents reacting to transient magnetic fields.

[438] Management of Ventilatory Insufficiency by Diaphragm and Thoracic Stimulation

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Sponsor: VA Rehabilitation Research and Development Center (Core Funds)

Purpose—Current methods of phrenic nerve stimulation to relieve chronic ventilatory insufficiency have created problems with nerve damage and diaphragm inefficiency and fatigue. Diaphragm inefficiency may be related to the paradoxical inward chest movements during inspiration that occurs when intercostal muscles are not activated. The goals of the present study are to develop improved functional electrical stimulation methods. Our approach will evaluate direct diaphragm stimulation to reduce problems of chronic nerve damage and to coordinate intercostal with diaphragm to improve efficiency and reduce fatigue problems.

Methodology—In acute dogs following anesthesia, single intramuscular electrodes were implanted in each hemidiaphragm close to the entry of the phrenic nerves, and bilateral electrode pairs were inserted deep into the chest wall to activate intercostal muscles. Ultrasonic crystals were inserted in the diaphragm for recording diaphragm shortening. Respiratory responses to electrical stimulation were recorded following hyperventilation-induced periods of apnea.

Progress—In preliminary studies, we found direct diaphragm stimulation alone capable of producing significantly large tracheal air flows. Intercostal

stimulation alone produced thoracic excursions but reduced tracheal air flows. Combined diaphragm and intercostal stimulation produced tracheal air flows greater than diaphragm stimulation alone. Diaphragm shortening measured with ultrasound crystals indicated that the thoracic stimulation did not alter diaphragm shortening, providing further evidence for the benefit of combined thoracic and diaphragm stimulation.

These results indicate the feasibility of direct diaphragm stimulation and the assistance provided by intercostal activation. We are now trying to optimize stimulating parameters and electrode placement to maximize the mechanical response.

Future Plans—We plan to determine if intercostal activity increases ventilatory efficiency and reduces fatigue during long-term diaphragm stimulation. In addition, active expiration with "cough" may be possible with selective abdominal stimulation, thereby introducing a naturally induced clearing mechanism for the airways.

Recent Publications Resulting from This Research

Management of Ventilatory Insufficiency by Coordinated Diaphragm and Thoracic Muscle Stimulation. Dunn RB, et al., 37th Annual Conference of the American Paraplegia Society, 20, 1991.

[439] Effect of Inspiratory Muscle Training in Quadriplegics

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Sponsor: American Association of Spinal Cord Injury Nurses

Purpose—This study will examine the effects of four months of inspiratory muscle training with a threshold pressure breathing device in 32 healthy stable persons with traumatic quadriplegia (level C4–C8).

Methodology—Participants will be randomly assigned to one of two groups: inspiratory muscle training (IMT) with an inspiratory load equal to 30% of their maximal inspiratory pressure or IMT with a sham load (<6 cm H₂O). Participants will exercise for 30 minutes each day, 7 days a week.

The effects of inspiratory muscle will be assessed with respect to the following: inspiratory and expiratory muscle strength as measured by the maximal inspiratory and expiratory pressure, respiratory muscle endurance as measured by the time to exhaustion while breathing against an inspiratory load equal to 66% of maximal inspiratory pressure, inspiratory capacity as measured with spirometry, expiratory capacity as reflected by the expiratory reserve volume and maximal expiratory flow rate, quality of life as measured by the Quality of Life Index, and respiratory symptoms and general energy level as measured by recordings in a daily training diary.

A full set of pulmonary function tests will be conducted at baseline and at the end of the study. Electromyograms of the respiratory muscles, arterial blood gases, and a history of pulmonary problems

(Clinical Questionnaire) will be taken at baseline. Data will be collected in a combination of laboratory and home visits. Before starting inspiratory muscle training subjects will complete a 3-week control period during which they attend three weekly practice sessions to learn to perform the tests which require physical effort. Baseline data will be measured at the fourth visit and then subjects will begin training. Their progress will be monitored monthly. Data will be analyzed with descriptive statistics and repeated measures analysis of variance.

Implications—Quadriplegic persons with spinal cord injuries between C4 and C8 experience both inspiratory and expiratory muscle weakness. Inspiratory muscle training may improve their health by increasing the strength and endurance of their inspiratory muscles and this may protect against respiratory muscle fatigue especially during acute lower respiratory tract infections. It may increase the inspiratory capacity to allow for deeper breaths and in turn better airway clearance. Increases in inspiratory muscle strength and endurance were documented in persons with chronic obstructive pulmonary disease following inspiratory muscle training. However, only one study examined the effects of inspiratory muscle training in spinal cord injured persons and further work is needed.

[440] Nurse-Managed Expiratory Muscle Training: Quadriplegia

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Sponsor: American Association of Spinal Cord Injury Nurses

Purpose—Quadriplegic persons with traumatic spinal cord injuries (SCI) between C4 and C8 experience expiratory muscles weakness that limits their ability to generate the forces required to produce an effective cough. This study will examine the effects of expiratory muscle training in healthy stable

persons with traumatic quadriplegia (level C4–C8) to determine if expiratory muscle training will increase the strength and endurance of expiratory muscles, improving the ability to cough and clear the airways of secretions, especially during acute lower respiratory tract infections.

Methodology—Participants will be randomly assigned to one of two groups: a treatment group of expiratory muscle training or a control group with sham expiratory muscle training. The treatment group will train their expiratory muscles with a pressure threshold breathing device using an interval protocol. Both groups will train for four months and the following will be measured at baseline and after each month of training: 1) respiratory muscle strength as measured by maximal expiratory and inspiratory pressure; 2) respiratory muscle endurance as measured by the maximal voluntary ventilation in 12 seconds; 3) inspiratory and expiratory capacity as measured by vital capacity, inspiratory capacity, and expiratory reserve volume; and, 4) ability to generate forces required for an effective

cough as measured by airflow, volume, and pressure at the mouth during three maneuvers: (a) voluntary forced expiration, (b) voluntary cough, and (c) involuntary cough.

Compliance with expiratory muscle training will be monitored with an innovative device designed to record the accumulated duration of expiratory muscle training. In addition, a full set of pulmonary function tests will be conducted at baseline and at the end of the study and arterial blood gases will be taken at baseline. Participants' perception of the intervention will be assessed after four months of training with a semistructured interview. Data will be analyzed with descriptive statistics and repeated measures by analysis of variance.

[441] Interpersonal Behavior and Adjustment of Persons with Spinal Cord Injury

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Sponsor: *American Association of Spinal Cord Injury Psychologists and Social Workers*

Purpose—This project is a comprehensive study of the effects of interpersonal behavior on adjustment following spinal cord injury (SCI). The major focus of the project is to determine the impact of personal assertiveness on patient adjustment and whether assertiveness is directly or indirectly predictive of psychosocial functioning and health status. The study is designed so that personal and environmental variables that could possibly moderate the effects of assertiveness on adjustment will be examined.

Methodology—The study will involve data collection from two sites. Patients served by the SCI Unit in the McGuire Veterans Administration Medical Center (Richmond, VA) and the SCI Unit of the Department of Rehabilitation Medicine at the Medical College of Virginia (Richmond, VA) will be asked to participate in a study of interpersonal behavior and adjustment following SCI. This project has been reviewed and approved by the research committees of both institutions. Pilot data has been collected and preliminary results are supportive of the major tenets of the project. Patients will be requested to complete measures of

personal assertiveness, depressive behavior, psychosocial functioning, and social support. Demographic data will also be collected, including patient age, time since injury, race, gender, type of lesion (complete, incomplete), and level of lesion. Follow-up data will be collected from medical records and this will include number of days spent in the hospital within the year following initial contact, number of urinary tract infections and decubitus ulcers, and the average severity rating of these within the past year.

Implications—It is predicted that patient assertiveness will be predictive of psychosocial and medical adjustment. It is believed that patients who are more assertive will be able to utilize social support relationships more effectively, and subsequently these patients will be less depressed, evidence higher levels of psychosocial functioning, and have fewer health problems over time. It is the primary objective of this study to determine the impact of personal assertiveness on adjustment following SCI. By establishing a clear and significant link between patient interpersonal behavior and adjustment, in-

terventions that improve and augment patient interpersonal skills will be empirically justified. This will

accent current psychological services available to those with SCI.

[442] Relationship Between Coping Strategies Assessed During Acute Rehabilitation and Adjustment to Spinal Cord Injury at Five-Year Follow-up

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Purpose—It is estimated that there are approximately 250,000 people with spinal cord injury in the United States and that this figure increases annually by 7,000 to 10,000 persons. Ironically, although the mortality rate from spinal cord injury has decreased because of advances in medical technology, there has also been an increase in the number of deaths of individuals with spinal cord injury attributable to potentially preventable causes, such as self-neglect, alcohol and drug abuse, or suicide. Estimates of preventable deaths have ranged from 8% to 34%. Similar estimates have been given for the occurrence of self-neglect, which has included such diverse definitions as noncompliance with medical regimens to self-injurious behavior. Poor psychological adjustment has been linked to preventable deaths in individuals with spinal cord injury. However, the factors contributing to successful adjustment are poorly understood. We plan to assess the impact of coping on adjustment following spinal cord injury and assess whether the importance of coping factors changes over time.

Methodology—In this study, 57 individuals with spinal cord injury who participated in a study during acute (inpatient) rehabilitation 5 years earlier will be asked to complete the same set of measures to assess

changes in the relationships among psychological distress, health locus of control, ways of coping, and adjustment. The measures to be administered include the SCL-90-R, the Ways of Coping Scale, the Multidimensional Health Locus of Control Scale, the Acceptance of Disability Scale, and the Vocational and Medical Complications Form. Multiple regression analyses will be used to assess the impact of coping strategies during acute rehabilitation on long-term adjustment. Spearman Rank Order correlations will be used to assess the likelihood that the use of specific coping strategies at Time 1 are predictive of coping strategies at Time 2. Multiple regression analyses will also be used to assess the role of current coping strategies on adjustment at Time 2.

Implications—This study will allow us to evaluate adjustment at different points in time, from acute rehabilitation to 5 to 6 years postinjury. It is our belief that psychological factors important to spinal cord injury adjustment change over time and that these changes have important implications for the choices and timing of interventions targeted to facilitate optimal adjustment following spinal cord injury.

[443] Coping Strategies in Traumatic Spinal Cord Injury: A Longitudinal Study

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Purpose—In response to loss, emotional sequelae to spinal cord injury were considered to follow a

sequence of adjustment stages of denial, depression, anger, blame, etc., similar to that reported in the

literature on death and dying. If patients did not become depressed, they were thought to be at risk for disturbed adjustment due to what was considered excessive denial. Treatment efforts were designed to assist patients in "working through" their loss by progressing through the stages of adjustment. Recent investigations have questioned the validity of these "stage" theories and have found little support for depression as a natural consequence to spinal cord injury. Research in the area of coping has suggested that adoption of certain coping strategies may lead some patients to satisfactory adjustment, experiencing little significant depression or distress.

The present investigation is designed to examine the coping process from acute injury to a point 2 years postinjury, using repeated measures of coping strategies, depression, distress, and self-care in a sample of 100 traumatic spinal cord injured patients of diverse ethnic and cultural backgrounds. Results of the investigation will assist treatment specialists in their management of the patient adjustment process during inpatient rehabilitation and outpatient follow-up, provide direction in determining cultural group needs related to coping with injury, and promote hypotheses for new and much-needed theoretical models of adjustment to spinal cord injury.

[444] Use of Belt and Pneumatic Exsufflation Methods for Noninvasive Airway Secretion Clearance

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Sponsor: Department of Health and Human Services

Purpose—The purpose of this research is to determine if two forms of mechanically assisted coughing can create adequate peak cough expiratory flows (PCEF) to facilitate airway secretion clearance for patients with incompetent respiratory muscle function.

Methodology—The Jamil, a device already on the market, consists of a wide belt which encircles the abdomen and lower chest. Both ends of the belt are attached to a device which tugs on the belt with variable force. The resultant compression assists expiratory flow which can aid in clearing airway secretions. The rate, force, and length of time that the belt is tugged is adjustable to simulate coughing or huffing.

A second form, that of mechanical exsufflation with negative pressure (MENP), involves the use of a positive pressure blower to insufflate the subject via an anesthesia mask. This is followed by an exsufflation produced by a rapid and sustainable drop in pressure. Insufflation and exsufflation pressures are independently adjusted for efficacy and comfort; maximum tolerated pressures or rapidly alternating but smaller pressures can be used to simulate coughing or huffing.

The relative efficacy of these two methods are being studied by measuring the PCEFs which can be produced by their use. For any technique to be effective, it is essential to create high expiratory flow rates coupled with a high expiratory pressure gradient between the mouth and the alveoli. Normal PCEFs range from 6 to 12 liters/sec depending on age and sex; 6 liters/sec or greater is necessary for effective coughing.

Preliminary Results—We have found that most neuromuscular patients with severely impaired expiratory muscle function typically use MENP cycles with pressure drops of 60 to 80 mmHg for airway secretion clearance. In 14 subjects studied thus far, 9 of whom were ventilator supported 24 hours a day, the unassisted PCEFs were 1.94 ± 1.70 liters per second. The PCEFs measured while using MENP were 7.14 ± 1.37 liters per second.

Only one of 14 subjects had PCEFs measurably increased by using the Jamil. This patient, with an unassisted CPEF of 1.0 liters, had a 1.58 liter per second PCEF when using the Jamil but he also had a 7.46 liter per second PCEF when using MENP.

Our preliminary results suggest that the Jamil is not effective in assisting cough or clearing airway secretions in patients with neuromuscular respiratory insufficiency. MENP is extremely effective and we will further explore its use in this patient population as well as for patients with high risk of pulmonary complications due to impaired oropharyngeal mus-

cles, recent abdominal surgery, and for patients with chronic obstructive or intrinsic pulmonary disease.

Recent Publications Resulting from This Research

Mechanical Exsufflation, Noninvasive Ventilation and New Strategies for Pulmonary Rehabilitation and Sleep Disordered Breathing. Bach JR, Bull N Y Acad Med (in press).

[445] Evaluation of Motor Recovery at the Site of the Lesion by Manual Myometry in Cervical SCI Patients

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Purpose—The major objective of this study is to identify the course of neural recovery following spinal cord injury (SCI). A qualitative evaluation of the strength and fatigue of muscles after SCI would assist in assessing the accurate progress of motor recovery. Despite intertester reliability, the manual muscle test is subjective and not sufficiently quantitative to detect changes in strength between muscles of good and normal grades. Therefore, this study is designed to compare hand-held and fixed myometric measures of force output to the manual muscle test to determine which is more accurate in identifying neural recovery. As part of the process of neural recovery, this study will also investigate the role of fatigue in the recovery of muscle strength.

Methodology—All C4-T1 complete and incomplete spinal cord injured patients admitted to the Regional Spinal Cord Injury Center of Delaware Valley within 72 hours of injury are included in this study. The patients undergo manual muscle testing and force transducer measurements of the biceps (C5), extensor carpi radialis muscle (C6), triceps (C7), flexor digitorum profundus (C8), and interossei (T1) muscles with a hand-held myometer. To compare the value of the hand-held myometer with fixed myometer measurements of strength, the extensor carpi radialis muscle is evaluated utilizing both techniques. The manual muscle test and force transducer measurements are performed at 72 hours and weekly until one-month post-spinal cord injury; then the manual muscle test, force transducer measurements and activity of daily living are evalu-

ated monthly for 1 month to 3 months and at 6, 12, 18, and 24 months post-spinal cord injury. The fatiguability of extensor carpi radialis muscles (ECR-C6) will be determined by use of a force transducer. The C4-C7 motor complete subjects whose ECR measure 2+ to 4+ at one month post-injury will be instructed to maintain an 80% isometric contraction by extending the wrist as long as possible. An abrupt decline (50%) in isometric force will reflect fatigue of the ECR. The time to decline will represent the fatigue time. ECR fatigue will be measured at 1, 2, 3, 6, 12, 18, and 24 months post-injury to delineate the changes during recovery and will be compared to strength measurements.

Future Plans/Implications—Recent findings in spinal cord injury research highlight the importance of accurate measurements of neurological recovery. The initiation of the methylprednisolone protocol in April 1990 gives our center a unique opportunity to compare the rate and extent of recovery in those spinal cord injured patients who did not receive high dosage steroids in the past to those who now receive high dosage steroids.

Recent Publications Resulting from This Research

Recovery of Strength in Motor Complete and Motor Incomplete Spinal Cord Injured Patients. Mange KC, et al., Arch Phys Med Rehabil 71:562-565, 1990.

A Simple Method for Evaluation of Neuromuscular Fatigue in Normal and Quadriplegic Subjects. Jaweed MM, et al., J Am Paraplegia Soc 13:54, 1990.

Recovery of Motor Strength as Predicted by Motor and Sensory Preservation in the Zone of Partial Preservation in Quadriple-

gia Subjects. Browne BJ, et al., *J Am Paraplegia Soc* 14:89, 1991.
 The 72-Hour Exam on a Predictor of Recovery in Motor Complete Quadriplegia. Brown PJ, et al., *Arch Phys Med Rehabil* 72:546-548, 1991.

Recovery of Zero-Grade Muscles in the Zone of Partial Preservation in Motor Complete Quadriplegia. Wu L, et al., *Arch Phys Med Rehabil* (in press).

[446] Evaluation of Motor Recovery Below the Site of the Lesion in Quadriparetic and Paraparetic Subjects

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Purpose—Approximately 90% of incomplete SCI subjects have cervical or thoracic lesions, and thus could potentially develop spasticity. Investigators found that 19% of rehospitalizations in persons with spinal cord injury were due to spasms. Moreover, of the medical complications reported in non-hospitalized SCI patients, 15% were due to spasms. The purpose of this study is to identify the relationship between the recovery of motor power and the evolution of spasticity in the spinal cord injured population. Since ambulation is a prime concern of individuals with SCI and is related to both motor power and spasticity, it is essential that both are measured throughout the recovery period to better guide the patient and caretakers concerning the chances of eventual ability to walk.

Methodology—All individuals with motor-incomplete paralysis (Frankel C and D) due to spinal cord damage from C4 to T12 who are admitted to the Regional Spinal Cord Injury Center of Delaware Valley within two weeks post-SCI will be included in this study. The subjects will be evaluated for spasticity and the voluntary force of contraction at 1, 2, 3, 6, 12, 18, and 24 months post-SCI. The spasticity of the dorsi and plantar flexors will be evaluated unilaterally by determining the passive resistance to angular displacement at 30 degrees, 60 degrees, and 90 degrees per second. The two voluntary concentric forces of contraction will be determined at the same angular velocities of 30 degrees, 60 degrees, and 90 degrees per second. Simultaneous integrated electromyographic (EMG) activity of the dorsi and plantarflexors will be performed during both the evaluation of passive tension and voluntary contraction. The speed of

therapeutic, household, and community ambulation will be evaluated when possible. A statistical analysis will be performed to relate the active force of contraction to the passive force of the antagonistic muscle contraction; similarly, the integrated EMG activity of the agonist muscles will be related to the integrated EMG activity of the antagonistic muscles. The relationship of agonist to antagonist force of contraction and EMG activity will be utilized to determine the extent of antagonist restraint on agonist muscle contraction. Criteria will be developed to predict the SCI subjects' ability to ambulate based on the development of ability to contract agonist muscles in the absence of antagonist muscle restraint.

Future Plans/Implications—The findings from this study will help to identify the role of motor recovery, reflex activity, and sensation in the prediction of future ambulation for individuals with motor-incomplete spinal cord injury. This information will allow rehabilitation professionals to better determine the course of treatment for patients with incomplete motor paralysis.

Recent Publications Resulting from This Research

Prognosis for Ambulation Based on Sensory Examination in Patients Who Are Initially Motor Complete. Crozier KS, Graziani V, Ditunno JF, *Arch Phys Med Rehabil* 72:119-21, 1991.
 Prognosis for Ambulation and Motor Recovery in Motor Complete Lower Motor (LMN) Spinal Cord Injury. Goldbaum ML, Crozier KS, Herbison GJ, Ditunno JF, *J Am Paraplegia Soc* 14:91, 1991.
 Quadriceps Recovery in Frankel C Spinal Cord Injury. Zorn GW, Crozier KS, Cheng LL, Herbison GJ, Ditunno JF, *J Am Paraplegia Soc* 14:90, 1991.
 Spasticity and Frankel Score After Cervical Spinal Cord Injury.

Duch J, Weinstein D, Herbison K, Formal C, J Am Paraplegia Soc 14:83, 1991.
 Spinal Cord Injury: Prognosis for Ambulation Based on Recovery of Quadriceps Function. Cheng LL, Crozier KS, Zorn G, Herbison GJ, Ditunno JF, J Am Paraplegia Soc 14:94, 1991.

Spontaneous Electromyographic Potentials in Chronic Spinal Cord Injured Patients: Relation to Spasticity and Length of Nerve. Campbell JW, Herbison GJ, Chen YT, Jaweed MM, Gussner CJ, Arch Phys Med Rehabil 72:23-27, 1991.

[447] Motor Unit Mapping in Extensor Digitorum Longus (EDL) Muscles of the Spinal Nerve Injured Rat

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Purpose—Early studies reported that spontaneous recovery of strength can occur after the nerves are partially injured. This may be due to a regrowth of the nerve from the point where it is severed to the muscles. However, this is not the only way that the strength might increase. The force of contraction can also improve because the muscle fibers that remain functional after the partial nerve injury might increase in strength, thus increasing the force of contraction. Finally, the small branches of nerves within the muscles can form extra branches to supply the muscle fibers that have lost their nerve supply. The purpose of the present project is to evaluate the impact of various exercise interventions on the recovery of strength. There is some evidence that overuse may impair function, whereas appropriate use of exercise enhances the course of recovery. This problem can be evaluated by determining the exact time course of recovery after partial nerve injury that mimics the type of injury to the nerves exiting from the spinal cord in a quadriplegic patient. This model of recovery has been evaluated in our laboratory and we are presently evaluating the effect of electrically-induced exercise on the process of recovery, and will determine the impact of other types of exercise on the course of recovery of strength after the muscle has been weakened by partial nerve injury.

Methodology—Four groups of control and four groups of unilaterally L4 spinal nerve injured (SNI) Sprague Dawley rats (body weight between 300-325 g) are in the process of being studied. The

SNI rat will undergo unilateral surface electrode stimulation of the peroneal nerve innervation of the extensor digitorum longus muscles one-half hour each day, 5 days per week, between 2 and 12 weeks post-SNI. The extensor digitorum longus muscle is evaluated for the peroneal nerve-evoked twitch and tetanic force of contraction. After completion of these force measurements, the muscles are activated at the rate of 10 Hz until the muscle no longer contracts. At this time the animal is sacrificed and the muscles are removed and stained for PAS to identify the number of glycogen-depleted fibers which reflects the extent of peripheral nerve sprouting. If the increased force of contraction is observed due to enhanced peripheral nerve sprouting from the electrical stimulation, there will be an increased number of glycogen-depleted fibers in the stimulated fatigued muscles compared to the nonstimulated muscles.

Implications—Since the extent of peripheral reinnervation of muscle is limited and reinnervation occurs within a limited area, it is essential to seek means that may enhance the number as well as the rate of growth of peripheral sprouts. A better understanding of the role of electrical stimulation in the peripheral nervous system may be used for exploring the recovery of the corticospinal tract neurons in the central nervous system. Further, appropriate dosages and extent of electrical stimulation must be developed in order to optimally deploy it for clinical treatment of spinal cord injured patients.

[448] Motor Power as a Predictor of Specific Functional Skills

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Purpose—The enhancement of functional status is the major outcome sought in rehabilitation. The extent to which this outcome has been defined has been variable. The validity of the efforts of rehabilitation professionals at intervention critically rests on the documentation of motor recovery in relation to functional improvement. A patient may have enough motor strength to perform a task once or for a limited time, but may have more difficulty with task repetition. With sufficiently sensitive instruments for measuring motor strength and functional skills over the first two years following spinal cord injury, the relationship between motor and functional recovery can be better elucidated. The purpose of this study is to accurately measure motor strength during the course of recovery from spinal cord injury and relate strength to function as assessed by the Quadriplegia Index of Function (QIF).

Methodology—All C4-T1, Frankel A-D spinal cord injured patients admitted to the Regional Spinal Cord Injury Center of Delaware Valley within two weeks post-injury will be included in the study. Motor power of biceps, triceps, extensor carpi radialis and flexor digitorum profundus will be tested weekly during the first month post-injury,

and thereafter at 2, 3, 6, 12, 18, and 24 months. The activities of daily living (ADL) skills will be evaluated at 1, 2, 3, 6, 12, 18, and 24 months. Motor power will be measured by the manual muscle test and with the use of a myometer. ADL skills will be measured using a modified QIF instrument. A statistical analysis will be performed to identify specific ADL that reflect performance in sub-groups of ADL and to correlate motor power to the capacity to perform specific ADL.

Preliminary Results—Initial data analyses of the QIF data investigated the relationship between muscle strength and independence in self-care activities at 6 months or greater post-spinal cord injury. The overall trend suggests that triceps of grade 3 or better in conjunction with functional biceps and wrist extensors may be necessary for independence in daily self-care activities.

Recent Publications Resulting from This Research

Triceps Strength as a Predictor of Daily Self Care in Quadriplegics. Demagone DA, Zafonte RD, Herbison GJ, Ditunno JF, J Am Paraplegia Soc 14:95, 1991.

Daily Self Care in Quadriplegic Subjects. Demagone DA, Zafonte RD, Herbison GJ, Ditunno JF, J Neurol Rehabil (in press).

[449] An Organized Approach to Cervical Central Cord Injury: Neurological Outcome of Early Versus No Surgery

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Purpose—There is a controversy among the experts in spinal cord injury regarding the management of cervical central spinal cord injury after trauma. Some believe that early surgery is necessary after the traumatic event, while others advocate a more conservative management. This study is designed to

determine if the rate of improvement and the final neurological outcome is better in the acute traumatic central cord injured patients who have early surgery, as compared to those who have later surgery, and those who do not have surgery. The acute cervical central cord injury syndrome is characterized by a

disproportionately greater loss of motor power in the upper extremities than the lower extremities, by bladder dysfunction, and by varying degrees of sensory loss below the level of the injury. This syndrome is observed with higher frequency in older patients, and it is thought that preexisting spinal stenosis plays a major role in sudden quadriplegia after minor trauma.

Methodology—All acute traumatic central cord injured patients between the ages of 40 and 70 will be asked to participate in this study. Those patients who agree to participate will be randomly assigned to one of two groups, early surgery versus late surgery (18-24 days post-injury). Only patients admitted to the Regional Spinal Cord Injury Center of Delaware Valley within 3 weeks post-injury will be considered for the study. They will be invited to participate if they do not improve over a 1-2 week period of time. Motor power evaluation will be performed prior to surgery, weekly to 5 weeks

post-spinal cord injury, and at 2, 3, 6, 12, 18, and 24 months post-spinal cord injury. Anterior decompression and fusion will be performed if there is anterior cord compression. A decompressive laminectomy will be performed when the spinal canal is compressed posteriorly from ligamentum flavum hypertrophy, canal stenosis, or when osteophytic narrowing of the canal involves more than three vertebral segments. A statistical analysis will be performed to determine the efficacy of early versus late cervical decompression in this group of patients. These data will also be compared to patients who do not receive surgery.

Preliminary Results—To date there have been 15 patients entered into the study; eight have had early surgery and seven have had no surgery. There was no apparent difference in recovery of motor sensory function between those patients who received surgery as compared to those who did not receive surgery.

[450] Evaluation of Neural Recovery After Rapid Closed Reduction of Traumatic Low Cervical Spine Dislocation

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—Reduction of cervical spine dislocations is often unsuccessful using skull-tong traction and weights below 50 pounds. The literature suggests that it is unwise to attempt closed reduction with weights in excess of 40-50 pounds because of the risk of overdistraction. As a result, open reduction and posterior fusion is often performed after a delay of many hours. To date, no data have been presented which show that application of high weights under controlled conditions has led to any neurological complications. Further, it is unknown whether rapid early closed reduction with weight in excess of 50 pounds will result in improved recovery of sensory and motor levels at or below the zone of injury. Because of preliminary reports that have suggested that it may be safe to apply heavy traction (weights in excess of 50 pounds), this project was designed to evaluate heavy traction as a safe means of reduction of cervical spine dislocations.

Methodology—Patients admitted to the Regional Spinal Cord Injury Center of Delaware Valley with traumatic spine dislocations or fracture-dislocations between C3 and C7 are included in this study. All patients (Frankel Grade A-D), over a 5-year period of time, with dislocations or fracture dislocation with more than 3 mm of displacement involving C3 to C7 will be included unless there is a fracture of the posterior vertebral body with retropulsion of free bony fragments into the neural canal. Reduction of the dislocation is performed on a Stryker frame using Gardner-Wells tongs applied to the skull with sequential weight increases. Neurologic levels and serial radiographs are examined and additional weights added approximately every 15 minutes until reduction is achieved (up to a maximum of 150 pounds). The time from injury to reduction is recorded for each patient. Formal neurologic evaluation, including the testing of mus-

cle strength and pinprick sensation evaluations, is performed before, during, and after reduction, as well as in conjunction with long-term follow-up. Data will be analyzed with respect to the time from injury to reduction compared with neurologic recovery. Further analysis will evaluate whether or not neurologic changes correlated with the time after injury to reduction.

Preliminary Results—Twenty-four patients have received traction since the inception of this study. All patients were reduced within a 2 and a half-hour period with weights of 40 to 140 pounds. There has been no evidence of acute neurological deterioration throughout the traction period and three patients improved during the traction period. Matched con-

trols were found for 12 patients. Analyses suggest that at 1 month those patients who received heavy traction showed a significantly greater increase in motor index scores than did control patients.

Future Plans—Because of these early results, data collection and analysis will continue.

Recent Publications Resulting from This Research

- Immediate Closed Reduction of Cervical Spine Dislocations Using Traction. Star AM, et al., *Spine* 15:1068-1072, 1990.
- The Medical and Economic Impact of Closed Cervical Spine Dislocations. Cotler HB, et al., *J Am Paraplegia Soc* 13:38, 1990.
- Rapid Closed Reduction of Traumatic Cervical Spine Dislocation Using Traction Weights Up to 140 Pounds. Cotler JM, et al., *Spine* (in press).

[451] Motor Evoked Potentials as a Predictor of Motor Recovery After Spinal Cord Injury

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Purpose—Despite significant research into acute spinal cord injury (SCI), accurate electrophysiological assessment of completeness of motor deficit and prediction of the degree of recovery of function are lacking. Somatosensory evoked potentials measure spinal cord sensory function, but only indirectly correlate with the degree of motor deficit in SCI. Even long-loop cortical motor reflexes are, at best, estimates of spinal cord motor conduction and have not been found valuable in assessing SCI patients.

Recent refinements of brain stimulation technique using a magnetic coil promise a safe and practical procedure for the study of motor evoked potentials (MEPs) in acute SCI. It is important that evaluations of MEPs by magnetic stimulation be developed as a precise clinical tool to investigate the problem of acute SCI and associated motor and functional deficits and recovery in man.

This study was designed to determine if MEPs induced by magnetic stimulation of the cortex in thoracolumbar SCI patients can be utilized to predict recovery or lack of recovery of motor power in the lower extremities.

Methodology—All SCI patients with complete and incomplete lesions between T2 and L1 who are admitted to the Regional Spinal Cord Injury Center of Delaware Valley within 72 hours of traumatic SCI, and who are medically stable, will be included in this study. MEPs and central motor conduction times (CMCTs) will be performed on the lower extremities at 1 week, 2-3 weeks, and 3-4 weeks post-SCI. These results will be correlated with the data on muscle strength as measured by the manual muscle test.

Preliminary Results—MEP studies on 20 patients, who have received at least two tests, show a significant relationship between motor power and the presence of MEPs. Patients who had preserved or recovered MEPs exhibited muscles of fair strength ($>3/5$). No subject who had unobtainable MEPs had recovered motor function by 2-3 months post-injury. Several subjects had recovered MEPs at 2-3 months post-injury, but muscle strength was $<3/5$; subsequent follow-up showed recovery at a later time.

Implications—If the MEP can be shown to be indicative of future motor recovery, and if the information is beyond that obtained from a standard neurological exam, then MEPs may be helpful in advising the patient, family, and other support systems in planning for future care needs.

Recent Publications Resulting from This Research

Motor Evoked Potentials as a Predictor of Motor Recovery After Spinal Cord Injury. Booth KR, et al., *Neurology* 40:285, 1990.

Motor Evoked Potentials and Central Motor Conduction: Studies of Transcranial Magnetic Stimulation with Recordings from the Leg. Booth KR, et al., *Electroenceph Clin Neurophysiol* 75:S13, 1990.

Useful Clinical Applications of Magnetic Coil Stimulation. Booth KR, et al., *Electroenceph Clin Neurophysiol* 75:21P, 1990.

Motor Evoked Potentials and Central Motor Conduction: Studies of Transcranial Magnetic Stimulation with Recordings from the LCS. Booth KR, et al., *Electroenceph Clin Neurophysiol* 81:57-62, 1991.

[452] Use of Somatosensory Evoked Potentials to Predict Recovery of Neural Function At and Below the Level of Spinal Cord Injury

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Purpose—The objective of this study is to utilize somatosensory evoked potentials (SEP) as a tool to identify the locus of recovery in order to predict motor and sensory recovery and function in spinal cord injured (SCI) subjects.

Methodology—All patients with complete and incomplete C5 to T1 lesions admitted to the Regional Spinal Cord Injury Center of Delaware Valley within one week of injury are invited to participate in this study. SEP analysis by stimulating appropriate nerves in the upper and lower extremities are evaluated in all patients within one week of the spinal cord injury. The following spinal nerve distributions are evaluated: C5-lateral antebrachial cutaneous nerve; C6-superficial radial nerve; C7-cutaneous nerves of the long finger; and, C8-ulnar nerve in the L5-S1 roots via the tibial nerve. SEP determinations are performed within one week and at 8-12 weeks post-injury. Amplitude, latencies, and waveform of the evoked potentials will be evaluated at segmental levels. Sensation is evaluated at segmental levels with bedside tests of pin and touch. Motor power at segmental levels is evaluated in the upper and lower extremities with the manual muscle test (MMT). Relating the SEPs to motor power and sensation, we will be able to predict the degree of functional improvement that will occur in spinal injured subjects.

Preliminary Results—A recent analysis investigated the value of SEPs in predicting the recovery of ECR strength at the zone of partial preservation in patients with lesions at C4 to T1, Frankel A-D. Twelve subjects whose initial ECRs were $<2.5/5$ were tested for SEPs of the median and superficial radial nerves within one week of injury. The waveform was qualitatively graded as: normal-to-mildly abnormal (2), moderately-to-severely abnormal (1), or absent (0). Subjects were periodically evaluated by MMT from 72 hours to 18 months post-injury. Six of the 12 subjects achieved ECR strength of $\geq 3.5/5$, and six subjects never achieved a functional grade ECR ($<3.5/5$). Of those subjects who achieved a functional grade ECR by 18 months: 50% had no SEPs (0) on initial testing; 33% had normal-to-moderately abnormal SEPs (2); and 17% had severely abnormal SEPs. In the group that did not achieve a functional grade ECR: 67% had no SEPs (0) on initial testing; 16.5% had either normal-to-moderately abnormal (2); or severely abnormal (1) SEPs. There were no statistical differences between these two groups, suggesting that the SEPs predictive value may be no better than chance.

Future Plans/Implications—Although preliminary results argue against using SEP to predict future

recovery, the sample size was too small to draw definitive conclusions. Therefore, data collection will continue. If it is possible through this study to better predict recovery of function, we can assist the patient and family in planning for the future. Secondly, if it is possible to identify improvement of a root at the zone of injury through this technique, we may assist the surgeon in identifying the relationship between the procedure and the eventual clinical outcome.

Recent Publications Resulting from This Research

- Recovery of Motor Power as Predicted by Sensory Preservation at the Zone of Spinal Cord Injury in Quadriplegic Subjects. Browne B, et al., Arch Phys Med Rehabil 71:795, 1990.
- Recovery of the Extensor Carpi Radialis Muscle as Predicted by Root Specific Somatosensory Evoked Potentials in Motor Complete and Incomplete Quadriplegia. Sarlo FB, et al., J Am Paraplegia Soc 14:66, 1991.
- Extensor Carpi Radialis Recovery Predicted by Qualitative SEP and Clinical Examination in Quadriplegia. Jacobs SR, et al., Arch Phys Med Rehabil (in press).

[453] Peripheral Sprouting as the Mechanism of Motor Recovery at the Zone of Injury After Traumatic Spinal Cord Injury

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Purpose—Although motor recovery at the zone of injury in spinal cord injured (SCI) patients is known to occur, the mechanisms which underlie this recovery have not been determined. Proposed mechanisms include neurapraxic recovery, overwork hypertrophy of muscle fibers, peripheral sprouting of the intact axons and axonal regeneration. Neurapraxic recovery would be expected within the first 6-8 weeks after injury. Axonal regeneration would not be expected in the forearm muscles for at least 12 months. It is likely that recovery between 1 and 6 months is due to peripheral sprouting of nerves and/or muscle hypertrophy. The purpose of this study is to determine through electrophysiologic studies whether peripheral sprouting occurs at the zone of injury between 1 and 6 months post-injury.

Methodology—All C5-C6 motor complete SCI patients between the ages of 18 and 60 years of age admitted to the Regional Spinal Cord Injury Center of Delaware Valley within 2 weeks of injury will be included in the study over a period of 5 years. The patients will undergo manual muscle testing of the biceps, extensor carpi radialis (ECR), and triceps muscles. The patients will also undergo conventional electromyography (EMG) and single fiber EMG of the ECR or biceps in C5-injured patients and ECR or triceps in C6-injured patients. These studies will

be performed at 1 month, 2-4 months, and 6-8 months post-injury. Changes in jitter and fiber density will be evaluated and related statistically to increases in strength by the manual muscle test.

Future Plans/Implications—Subjects will continue to be enrolled in this study through 1992, at which time data analyses will begin. The object of this study is to identify the time of peripheral reinnervation in the muscle by utilizing modern techniques of single-fiber EMG which would localize newly reinnervated muscle fibers generating a phenomenon known as jitter. By evaluating jitter and fiber density during the course of recovery, and muscle strength, it should be possible to identify various phases of recovery. If the strength of a muscle increases without any evidence of reinnervation, the recovery can be attributed to either the elimination of neurapraxic state or to muscle hypertrophy. If it is accompanied by increased jitter and fiber density, then it can be attributed to peripheral sprouting. It is essential to identify the contribution of peripheral sprouting to help define its contribution to the recovery of motor power. Without this data, it is difficult to determine the contribution of and best mode of utilization for various treatment strategies to recovery.

[454] Recovery of Upper Extremity Muscles Following Cervical Spinal Cord Injury

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Purpose—Research has shown that a relationship exists between muscle strength and function following spinal cord injury (SCI). Therefore, it is important to be able to determine the course and extent of motor recovery following SCI. Normative data on both the degree of recovery at time intervals post-injury, and the time required to reach maximum strength after the onset of injury, has not been presented in the literature. These data would enable clinicians to predict the degree of motor recovery in cervical SCI patients and to identify the effects of pharmacological, surgical, and rehabilitative interventions on the course of recovery. A major multicenter, multiyear study is needed to obtain the data necessary to determine normative recovery rate and extent. Further, a multicenter study would enable the results to be generalized beyond one center and its associated modes of treatment. This study is a collaborative initiative of the Regional Spinal Cord Injury Systems in New York, Birmingham, Downey, and Philadelphia. This study will expand on a recent multicenter project which investigated biceps and wrist recovery.

Methodology—Patients with SCI, C4-C8, Frankel A-D who are between the ages of 15 and 70, in each of the collaborating model SCI system centers will have sequential motor strength examinations if possible, immediately post-injury, 72 hours, 1, 2, 3,

4 weeks, and 2, 6, 12, 18, and 24 months post-injury. A modified manual muscle test (MMT) will be performed on the biceps, extensor carpi radialis, triceps, and flexor digitorum profundus. Inter-rater and intra-rater reliability will be determined to insure that all centers are consistently and properly performing the MMT.

Data will be analyzed for the extent of recovery at specific time intervals, and for the percentage of individuals at each neurological level of injury and Frankel grade who achieve that extent of recovery. Normative data relative to the recovery of muscle strength will be established to serve as a basis for future analysis of therapeutic interventions.

Preliminary Results—Patient enrollment has begun. Data analysis will not be conducted until a sufficient number of subjects have been tested.

Implications—Information from this study will allow clinicians to better predict recovery from SCI and to determine when to best initiate therapeutic interventions.

Recent Publications Resulting from This Research

Motor Recovery of the Upper Extremities in Traumatic Quadriplegia: A Multicenter Study. Ditunno JF, et al., Arch Phys Med Rehabil (in press).

[455] Curved Catheter as a Measure of Preventing Atelectasis and Pneumonia in Spinal Cord Injured Patients

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Purpose—There is a high incidence of left-sided pulmonary complications in the acute spinal cord injury (SCI) patient. A recent study at the Regional Spinal Cord Injury Center of Delaware Valley

revealed a 4:1 ratio of left- versus right-sided pulmonary involvement for atelectasis and pneumonia (A/P). The literature documents that it is difficult to suction secretions from the left lung with

standard suction catheters due to the anatomy of the left mainstem bronchus. Curved-tip catheters can be more consistently inserted into the left mainstem bronchus, although the ability of curved-tip catheters to reduce the incidence of pulmonary complications has not been documented. The purpose of this study is to compare straight suction catheters to curved-tip catheters in reducing the incidences of pulmonary complication in acute SCI patients.

Methodology—Patients with acute traumatic cervical SCI (C1-C8, Frankel Grade A-C) who are admitted to the Regional Spinal Cord Injury Center of Delaware Valley within 72 hours of injury and are at risk for intubation or tracheostomy will be asked to participate in the study. Subjects will be randomized into two groups (straight versus curved-tip catheter) and stratified into two subject sets based on motor level (C1-C4 versus C5-C8). Chest radiographs will be obtained on day 1 and weekly for 30 days post-injury. Patients will be evaluated for incidence of A/P, as well as length of stay in the acute care hospital. The study will be divided into three phases: 1) evaluation and training; 2) data collection; and, 3) analysis of results.

Preliminary Results—The evaluation phase of this

experiment began in October 1990. During this period, two curved catheters have been evaluated for ease and accuracy of insertion. We have also been evaluating a means of marking the catheter for X-ray identification of placement. The training and data collection phases will begin in the coming year, once a catheter has been chosen.

Future Plans/Implication—Once training has been completed, the data collection phase of the study will begin. Pulmonary complications are the most frequent source of morbidity and mortality among SCI patients. The most common pulmonary complications in the acute post-injury period are A/P. The incidence of respiratory complications is related to the degree of compromise of the muscles of respiration. The left lower lobe appears to be particularly susceptible to A/P in hospitalized patients. This study will look at the use of selective suction catheters to determine whether their use results in decreased incidence or severity of pulmonary complications.

Recent Publication Resulting from This Research

Atelectasis and Pneumonia in Acute Spinal Cord Injury.
Fishburn MJ, Marino RJ, Ditunno JF, Arch Phys Med Rehabil 71:197-200, 1991.

[456] Motor Complete Spinal Cord Injury: Prognosis for Ambulation

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Purpose—Research has suggested that a relationship exists between preservation of pin sensation after a motor complete spinal cord injury (SCI) and recovery of motor function with eventual ambulation. Therefore, it is important to be able to determine at what point the presence of pin and touch post-SCI is a positive prognostic factor for future ambulation. This would enable clinicians to accurately predict ambulation soon after SCI. This study is designed to determine: 1) at what point post-spinal cord injury is the presence of pin and touch sensation a predictor for future ambulation; 2) to what degree do these patients become ambulatory; and, 3) if there is a difference in prognosis between patients with sensa-

tion limited to light touch and those with pin and touch.

Methodology—Quadriplegic and paraplegic subjects who are admitted to the Regional Spinal Cord Injury Center of Delaware Valley within one week of injury will be enrolled in the study if they are medically stable, motor complete but sensory incomplete (Frankel B) and have an upper motor neuron type injury. Therefore, levels of injury will be restricted from C4 to T10. Subjects will be tested on admission, at 72 hours post-injury, once a week for one month, and at 2, 3, 6, 12, and 24 months post-SCI.

The sensory exam will be done with a safety pin to access pin appreciation and by the finger to access touch appreciation, using a 3-point scale of absent, decreased, or normal. Sensory exams will be performed on the lateral aspect of the thigh, medial aspect of the knee, medial malleolus of the tibia, dorsal aspect of the proximal phalanx of the third and little toes, the penis or clitoris, and the perianal area. The subject's level of ambulation will be evaluated as appropriate at the same intervals as the

sensory examination and will be defined as a reciprocal gait. Three categories of ambulation will be identified: exercise, household, and community.

Future Plans/Implications—Data acquisition began in September 1990. Once sufficient data have been collected, they will be analyzed to determine when sensation best predicts future ambulation, and if light-touch appreciation alone is sufficient to predict ambulation.

[457] Longitudinal Analysis of Well-Being in Persons with Spinal Cord Injury and Their Caregivers

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Purpose—Much of the research in spinal cord injury is focused on acute care, with little attention being directed toward long-term coping and adjustment. There has been accumulating evidence of the importance of social support in the adjustment/coping arena. The purpose of this project is to investigate, on a longitudinal basis, the relationship between caregiver mental and physical health and the emotional and physical well-being of the person with spinal cord injury.

Progress—Ten caregivers/spinal cord injury individuals have been entered into the study. A study protocol has been developed consisting of well-

validated psychometric instruments. This is administered to caregivers during acute care hospitalization prior to discharge essentially as an "anticipated" burden of care assessment. The same battery is then repeated 1 month, 3 months, and 1 year post-discharge.

Methodology—This is a longitudinal design which will require multivariate techniques for analysis. Lisrel analysis and hierarchical regression techniques will also be utilized.

Future Plans—This project will continue through May 1994.

[458] Influence of Age on Rehabilitation Outcome of Persons with Spinal Cord Injury

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Purpose—As the median age of the U.S. population has increased, special attention is now being given to the health care needs of older persons. Even though most people with spinal cord injury (SCI) are relatively young, the health care needs of the subpopulation of older people with SCI may vary enough from their younger counterparts to suggest a

need for alternative treatment modalities.

The purpose of this study was twofold: Phase I examined the influence of age at the time of SCI on various demographic, process-oriented, and short-term outcome factors; Phase II examined the longer-term impact on the health care delivery system of an aging population with SCI.

Methodology—All patients enrolled in the National SCI database were included in this study. During Phase I, all patients were divided into six age groups in 15-year intervals. Demographic, process-oriented, and short-term outcome factors were compared for each age group, either by calculating the percentage of patients with each factor in each age group and then using the Chi-square test, or by calculating the arithmetic mean for each variable in each age group and then using the Student's *t*-test. Multivariate techniques such as analysis of variance, multiple linear, and logistic regression were used to control for the possible confounding effects of appropriate co-variables such as neurologic level and extent of lesion.

Phase II was a cross-sectional study comparing current age with outcomes during the current follow-up year. The data were analyzed in essentially the same manner as in Phase I.

Preliminary Results—The Phase I data set included 12,418 patients who sustained spinal cord injuries between 1973 and 1987. Mean number of days from injury to admission to the specialized treatment facility, days hospitalized and inflation-adjusted hospital charges decreased with advancing age at injury, while the percentages of ventilator dependent patients and patients discharged to nursing homes increased. Patients in the oldest age group were most likely to have had neurologically incomplete cervical injuries (usually Frankel class D motor functional lesions) resulting from falls and least likely to have improved neurologically. Two-year mortality rates for patients in the oldest two age groups were 6.7 and 7.4 times greater than for 16–30 year olds. These data showed that age at injury was

a highly significant predictor of rehabilitation outcome, with older patients having a comparatively poor prognosis. Moreover, because the relationships between age and outcomes were often nonlinear, the confounding effects of age must be carefully controlled when conducting future outcome studies.

The Phase II data set included current information on 11,117 patients who sustained spinal cord injuries between 1973 and 1989. Average time after injury was 4.7 years (range = 1–16 years). The percent of patients who were independent in self care decreased from 61.9% (age 16–30) to 29.1% (age 76+) ($p < 0.0001$). Only 28.7% of persons in the oldest age group independently ambulated. Ventilator use increased from 1.7% (age 16–30) to 4.3% (age 76+) ($p < 0.0001$).

Nursing home residence increased from 1.4% (age 16–0) to 22.2% (age 76+) ($p < 0.0001$). The percent of persons hospitalized during the previous year increased from 26.5% (age 16–30) to 33.7% (age 76+) ($p < 0.0001$). In general, age was an important predictor of health status, but time postinjury was less important, perhaps due to the short postinjury time frame during which the study was conducted. While few significant differences occurred from 16 to 60 years of age, dramatic health status changes occurred in the two oldest age groups.

Recent Publications Resulting from This Research

Effect of Age on Rehabilitation Outcomes of Spinal Cord Injury Patients. DeVivo MJ et al., *Asia Abs Dig* 16:6, 1990.

Effect of Age on Rehabilitation Outcomes of Spinal Cord Injury Patients. DeVivo MJ et al., *Arch Phys Med Rehabil* 71:787, 1990.

Relationship Between Age and Current Health Status for Persons with Spinal Cord Injury. DeVivo MJ et al., *Arch Phys Med Rehabil* 72:774, 1991.

[459] Medical and Psychological Considerations Regarding the Surgical or Pharmacological Treatment of Impotence in Males with Spinal Cord Injury

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Purpose—Erectile dysfunction is prevalent in the spinal cord injury (SCI) populations as well as in other males with various forms of spinal cord dysfunction. For the last 15 years, various penile

implants have been developed and utilized for erectile dysfunction; recently, pharmacological interventions have become available as well. Much of the existing literature concerning both of these proce-

dures, particularly as it relates to SCI, has been focused on medical and/or physical complications, with very little attention paid to the impact of these procedures on sexual behavior, sexual satisfaction, and/or relationships. This study will prospectively evaluate the impact of both implant and injection procedures on sexual behavior, sexual satisfaction, and relationships in the SCI population.

This study seeks the: 1) development of criteria for inclusion for potential treatment candidates; 2) development of the assessment procedures; 3) assessment of sexual behavior pretreatment and posttreatment in both the individual with SCI and his sexual partner; 4) assessment of sexual satisfaction pretreatment and posttreatment in both the individual with SCI and his sexual partner; and, 5) determination of the incidence of mechanical and/or medical complications posttreatment.

Methodology—All couples are screened for evidence of relationship stability and desire to comply with the study protocol. In addition, they are assessed for psychological and physical health, including evidence of drug and/or alcohol abuse, prominent depression, and marital discord. Individuals showing evidence of any of these problems are referred to appropriate counseling or other treatment before beginning either the implant or injection procedure.

Once screening has been completed, a battery of sexual behavior and satisfaction scales is initiated. Three months after the procedure has been completed, the couple repeats the same battery of forms.

Preliminary Results—Over the past grant year we identified, on average, two potential participants per month. However, many of these persons are excluded from the study for various reasons, including: 1) the absence of a regular partner; 2) inadequate reading ability; and, 3) poor physical and/or emotional health. Only a few candidates who have agreed to an implant or injection have refused to participate in this project.

To date, 17 couples have completed the protocol. The study was listed in our newsletter, *Pushin' On*, to increase the supply of potential candidates. Very preliminary results suggest that these interventions do not appear to make a major impact on sexual behaviors and/or frequency, but sexual self-esteem scales do seem to reflect improvement, more for SCI males than for their partners.

Future Plans—We are in the process of analyzing final results and will be disseminating and rewriting this information with journal submissions and presentations at national meetings.

[460] A Comprehensive Approach to Management of Infertility in Males with Spinal Cord Injury

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Purpose—Infertility is a major problem among male spinal cord injury (SCI) patients. In fact, infertility rates range from 99 percent for neurologically complete quadriplegics. This study seeks to: 1) determine optimal conditions for producing seminal emission via electrical stimulation of the pelvic sympathetic nerves; 2) compare electrical stimulation with strong vibratory stimulation of the genitalia in eliciting seminal emission in male SCI patients; 3) determine if repeated stimulation improves semen quality (sperm count, motility, and morphology); 4) determine if intermittent testicular cooling improves

semen quality; 5) relate success or failure of seminal emission production to neurologic level and extent of spinal lesion, urodynamic assessment of lower urinary tract function, and incidence of recurrent urinary tract infection; and, 6) artificially inseminate a male SCI patient's female partner who has been unable to be impregnated since the patient's injury.

Methodology—Male SCI patients voluntarily participating in the study will be assigned to a 2- to 3-month trial in the vibratory stimulation group. Seminal emissions will be acquired and sperm

counted and examined for viability. Patients failing to produce viable sperm will be entered into the electrical stimulation group if they wish to proceed. Patients who continue to fail to produce adequate numbers of viable sperm will undergo stimulation with testicular cooling. Caffeine stimulation will be performed on selected specimens to evaluate its effectiveness on improving sperm motility.

If these techniques produce no improvement in semen quality, the patient will be given the opportunity to participate in a study of direct aspiration of sperm from the surgically exposed vas deferens. Viability of sperm produced will be determined. The concomitant success or failure of seminal emission production will be assessed statistically. Female partners of patients with satisfactory sperm production will be evaluated physically and if in good health, artificially inseminated.

Preliminary Results—Forty-six patients have been entered into the study. A total of 22 patients have attempted vibratory stimulation techniques. Twenty-one patients have undergone electro-ejaculation. One patient has undergone a vas deferens aspiration of spermatozoa.

Of the 22 patients that have used the vibrator regularly, seven have reported results. Four of these patients have reported consistent ejaculations, two have reported inconsistent ejaculations, and one patient has been lost for follow-up. Of the four patients reporting consistent results, three have produced specimens within normal limits. The other patient produced a specimen with 30% motility and 45% morphology. The three patients producing normal specimens have been referred to a fertility specialist, and two of these patients' spouses are performing inseminations at home with no resulting pregnancy to date.

A total of 76 electro-ejaculations have been

performed on the 21 patients undergoing stimulation trials. Specimens with at least some evidence of sperm have been reported approximately 95% of the time. Low motility continues to be the most significant negative finding (<10%). One patient recently underwent electro-ejaculation on three separate occasions; motility improved from 0% to 10% with counts ranging from 0.8×10^6 cells/ml to 1.64×10^6 cells/ml. He was placed on intermittent testicular cooling for 2 to 3 months. Repeat electro-ejaculation produced a specimen with 10% motility and a count of 661×10^6 cells/ml. Five other patients have tried testicular cooling; there is not enough data to make any definite conclusions, and results appear to be inconsistent for the small sample at this time. No further studies of caffeine stimulation have been attempted, since early results proved to be insignificant. Four patients have been referred to a fertility specialist. Three couples have undergone inseminations. A total of six inseminations have been attempted, with no pregnancy reported.

One specimen has been collected using the vas deferens aspiration technique. There was significant improvement in the motility (0% to 50%); however, this specimen was of very small volume (0.2 ml). The specimen showed a count of less than 1×10^6 cells/ml. Artificial insemination was attempted with this specimen, but no pregnancy was achieved. This technique may prove most useful in the future using *in vitro* techniques.

Future Plans—We will continue to collect data and attempt to improve the fertility status of SCI males; however, we have begun charging for the electro-ejaculation. Also, the patient is now billed for all laboratory fees. A final report will be written at the end of this year and will be submitted for publication and presentation.

[461] Natural History and Clinical Course of Skin Complications (Excluding Pressure Ulcers) in Persons with Spinal Cord Injury

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Sponsor: National Institute on Disability and Rehabilitation Research

Purpose—Persons with spinal cord injury (SCI) frequently develop an array of potentially serious skin complications in addition to the more dramatic pressure ulcer typically associated with spinal paralysis. Examples include superficial and deep bacterial and/or fungal infections, furuncles, abscesses, dermal fibrosis, paronychia, and a host of related changes affecting the nail plate, bed, and wall. Our experience is that nonpressure ulcer skin complications represent a more significant and serious source of morbidity in this population than generally acknowledged.

The objectives of this study are to: 1) establish a clinically useful method to document the occurrence, etiology, definitive characteristics, management, and treatment outcome(s) of all nonpressure ulcer skin lesions occurring in a series of patients with SCI; 2) determine the nature of the relationship(s), if any, between nonpressure ulcer skin lesions in patients with SCI and specific characteristics of the spinal injury itself (e.g., neurologic level and extent of lesion, time post-injury, etc.); and, 3) develop, print, and distribute a clinically-oriented, teaching/training monograph devoted to the photographic documentation and description of nonpressure ulcer skin lesions in patients with SCI.

Progress/Methodology—A data collection instrument has been developed, refined, and field-tested to document nonpressure ulcer skin complications in patients with SCI. A history is obtained and a physical examination is performed at the patient's

annual follow-up examination. A clinical nurse specialist examines the patient's skin and completes the data collection forms. Data are obtained by actual observation of the patient. When possible, a diagnosis of the skin lesion(s) is made. Skin lesions are documented by photographs. When appropriate, bacterial and/or fungal cultures are acquired and appropriate treatment is given.

The analysis will be stratified by potential risk factors such as neurologic level and extent of lesion, age group, sex, and time post-injury. A high-quality, clinically oriented monograph will be produced by the project team.

Preliminary Results—Data have been collected on 514 patient visits. It is still too early to analyze the data in any depth; however, we are starting to look at trends in the data, especially the clinical grades of dermal thickening. Dermal thickening is present to at least a mild degree in the majority of patients. It is also obvious that dermal thickening is much more common and often more severe in patients with higher levels of spinal cord injury.

We are continuing to take photographs of interesting skin lesions which may be used in the monograph at the end of the study.

Future Plans—The goal is to obtain data on 250 to 400 patients annually. As additional data become available, preliminary analyses will be made to evaluate the progress of the study.

[462] A Clinically Derived Protocol for Changing Condom Catheters in Males with Spinal Cord Injury

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Sponsor: National Institute on Disability and Rehabilitation Research

Purpose—While meticulous hygiene and observation of the condom catheter and penis is consistently advocated, a disagreement exists on how often the condom catheter needs to be routinely changed. Recommendations range from changing it twice a day to changing it every few days. In fact, several of the most highly regarded nursing texts make no recommendation on how frequently it should be changed. Failure to reach a consensus on this issue is undoubtedly the result of the lack of any meaningful data upon which to base this clinically important decision.

The objectives of this randomized controlled clinical trial are: 1) to determine the incidence of urinary tract and penile skin complications for male patients with spinal cord injury (SCI) whose condom catheters are changed daily, every other day, or every third day; and, 2) to develop a protocol for routine changing of those catheters.

Methodology—The study population will include all male patients with SCI admitted to our hospital who use condom catheter urinary collection devices, are asymptomatic for urinary tract infection for at least 48 hours, and are free from other urinary tract and penile skin complications at the time of entry into the study.

Subjects will be randomly assigned to one of three groups: 1) patients whose condom catheters

are changed every day (Group I); 2) changed every other day (Group II); and, 3) every third day (Group III). Routine inspection of the penile skin will occur whenever the catheter is changed regardless of study group assignment. Total study population will be 87 patients. The duration of the study will be 30 days for each patient. A single brand of condom catheter has been selected and will be used for all study subjects. Patients having numerous accidents related to an improperly fitting catheter will be dropped from the study. At the conclusion of the study, a protocol will be developed from routine changing of these catheters.

Preliminary Results—During the past year, there has been a continuing problem in obtaining study subjects, the 30-day time factor being the major obstacle (many patients are discharged before they can complete the study). It was decided to delete the third study group and include only patients in the first two groups. In addition, to increase the sample size, patients from the SCI outpatient department will be included. The nurse clinician in the clinic will assess dependability and obtain patient consent to participate. Currently, 16 inpatients and 121 outpatients have participated in this study.

Future Plans—Plans are to continue enrolling patients in this study.

[463] Pathologic Effects of Recurrent Bacteriuria in Patients with Spinal Cord Dysfunction

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Purpose—Urinary tract infections (UTIs) are a serious source of morbidity for spinal cord injury (SCI) patients. Recurrent hospitalizations and outpatient services required for treatment of acute and

chronic UTIs are extremely expensive and may impede both the rehabilitation process and vocational pursuits. In addition, UTIs may lead to grave urologic complications and, in some cases, eventual

renal failure. There is a need to prevent these infections and their sequelae; this would improve the overall rehabilitation potential and quality of life for SCI patients.

Objectives of this study included: 1) determination of the incidence of clinically significant urinary tract complications coincident with the major bacterial species; 2) determination if aggressive treatment of most pathogenic organisms results in fewer long-term secondary urinary tract complications; 3) determination whether patients with certain human leukocyte antigen (HLA) combinations are at unusually high or low risk for developing long-term secondary urinary tract complications; 4) determination whether the phagocytic activity of human leukocytes correlates with the incidence of clinically significant UTIs and long-term secondary complications; 5) determination of the prevalence of *Mycoplasma hominis* and *Ureaplasma urealyticum* in lower and upper urinary tract (where possible in selected patients with spinal cord injuries), and the association of these organisms with various pathologic conditions, with particular emphasis on upper urinary tract disease and calculi.

Methodology—Records of SCI patients evaluated in the outpatient clinics at Spain Rehabilitation Center are being evaluated to determine the presence of UTI, the species of organisms involved, and type(s) of urologic complications which occur over time.

A group of patients (subjects) who are chronically infected and have diminished renal function and a separate group (controls) who have consistently sterile urine or whose sole complicating diagnosis is bacteriuria, have been identified from our patient database. Twenty-four patients from

each of these two groups have been given tests performed at the time of their annual urologic evaluation to determine the phagocytic abilities of their peripheral blood neutrophils, and for the determination of HLA haplotypes. Leukocyte phagocytic activity will be correlated with incidence of clinically significant urinary tract complications and with particular HLA combinations. Finally, the prevalence of mycoplasma in urine specimens from SCI patients will be determined.

Preliminary Results—Neutrophil phagocytosis assays have been performed on 24 patients from the experimental group and 24 from the control group for a total of 48 since August, 1988. No apparent difference in the phagocytic activity in the two groups has been observed thus far. Results are being analyzed.

HLA antigens have been determined on leukocytes from 48 patients, thus far, in an attempt to determine whether an association exists between a particular HLA haplotype and predisposition to urologic complications following SCI. The results are being evaluated.

Urine screening for mycoplasmas has been performed on 793 specimens, with positive cultures identified in 103. Repeated positive cultures over time in some patients have been observed. The distribution of positive cultures, the presence or absence of concomitant bacterial species, and possible clinical implications of these microbiological results are being evaluated.

Future Plans—The study has been completed and results are being evaluated.

[464] Natural History and Clinical Course of Urinary Tract Complications in Patients with Spinal Cord Dysfunction

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Sponsor: National Institute on Disability and Rehabilitation Research

Purpose—Appropriate clinical management of patients with neurogenic bladders resulting from spinal cord dysfunction requires: 1) knowledge of the natural history or clinical course of urinary tract

complications in this group; and, 2) data from which to determine if urinary complications in this group are predictable from early post-injury urinary tract status and method of early bladder drainage

management. The objectives of this study include: 1) to document the natural history and clinical source of urinary tract complications in persons with spinal cord injury (SCI) by continuing to build a urology database; 2) to answer specific research questions addressing the effects of (a) various bladder drainage management methods; (b) various bacterial pathogens; and, (c) various demographic factors (including age, sex, etc.), on long-term renal function, measured by effective renal plasma flow (ERPR), and the development of urologic complications including orchitis and/or epididymitis, penoscrotal abscess, penoscrotal fistula, ureterectasis, pyelocaliectasis, and calculi in a population with SCI; and, 3) to develop, refine, and offer for extramural acquisition a transportable urologic complication data collection protocol and its associated database.

Methodology—Data are collected for each patient admitted to the University of Alabama at Birmingham-Spinal Cord Injury Care System (UAB-SCICS) at admission, discharge, and annually thereafter. In addition, data have been collected retrospectively on 596 patients admitted to the UAB-SCICS between 1970 and 1979; prospective data are collected on these patients as they return for their annual follow-up examinations.

Preliminary Results—Complete studies have been performed and data recorded on 327 patients from a retrospective study group and 921 patients from a

prospective group, thus yielding 1,248 completed studies to date.

Future Plans—Research questions which may be addressed during the next project year include: 1) When are persons with SCI at greatest risk for developing clinically significant urologic complications? 2) What is the optimal schedule for routine urologic follow-up of persons who have experienced a spinal cord injury? 3) What is the effect of external sphincterotomy on long-term urologic function in persons with spinal cord injury? and, 4) Are the consequences of renal calculi more serious in older than younger persons with SCI?

The publishers of the *Physical Medicine and Rehabilitation Clinics of North America* continue to work with staff members of this project to prepare a special publication relating to the neurogenic bladder and its secondary complications along with their prevention and treatment.

Recent Publications Resulting from This Research

Epidemiology and Importance of Urinary Tract Infections in Spinal Cord Injury. Waites KB, presented in a colloquium on Prevention of Secondary Disabilities in People with Spinal Injury, Centers for Disease Control, Atlanta, GA, February 1990.

Norfloxacin Treatment of Nosocomial Urinary Tract Infection in Patients Undergoing Intermittent Catheterization Following Spinal Cord Injury. Waites KB, Canupp KC, DeVivo MJ, *Cur Ther Res*, 48:503-511, 1990.

Surveillance of Secondary Disabilities in Spinal Cord Injured Patients and Progress in Urinary Tract Epidemiology Study. Waites KB, presented at the Disabilities Prevention Project Workshop, Centers for Disease Control, Atlanta, GA, June 1990.

[465] Ultrasound for Urinary Tract Surveillance of Persons with Spinal Cord Injury

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Purpose—The purpose of this study is to determine the role of the renal ultrasound examination (RUSE) in the long-term urologic follow-up of persons with spinal cord injury. Patients with SCI require long-term surveillance to detect and treat urinary tract dysfunction. Because such dysfunction is often asymptomatic, continued screening of patients who

appear to be doing well is important. Screening of the urinary tract requires an examination that is sensitive, specific, easily performed, well-tolerated by the patient, and cost effective. The RUSE is less invasive than either excretory urography (EXU) or comprehensive renal scintigraphy (CRSP) and, therefore, might further increase the likelihood of

patients returning for routine annual evaluations. The RUSE eliminates the risk of ionizing radiation, can be performed in considerably less time than CRSP, and costs substantially less to perform.

Objectives of this project are to: 1) determine the sensitivity and specificity of the RUSE compared with CRSP for detecting upper urinary tract abnormalities of persons with SCI; 2) determine the sensitivity and specificity of the RUSE compared with EXU for detecting upper urinary tract abnormalities of persons with SCI; and, 3) determine the role of the RUSE in the long-term urologic follow-up of persons with SCI.

Methodology—Standardized data collection instruments and syllabus will be developed. At this RRTC, CRSP is routinely performed on all patients with SCI who have neurogenic bladders prior to first definitive discharge and annually thereafter. CRSP results are reviewed by both a nuclear medicine physician and a urologist. These results are compared with both published norms for the SCI population and the patient's prior test results, taking into account normal year-to-year fluctuations in asymptomatic patients.

The RUSE will be performed on a random sample of 10% of patients scheduled for routine CRSP. The RUSE will be performed using an ACCUSAN 128 Real Time ultrasound scanner utilizing 3.5 and 5.0 Mhz transducers. All tests will be performed under the supervision of Dr. D. Bradley Koslin. Results of other examinations will not be known by the ultrasonographer at the time of the RUSE. Renal size, parenchymal thickness, presence,

size, and location of calculi; presence, size, location, and character of renal masses; presence and severity of hydronephrosis; size of ureters (normal or enlarged); bladder volume and anterior wall thickness; presence of other abnormalities; and the overall quality of the examination will be recorded. Overall, at least 50 patients will receive both the RUSE and CRSP within 2 weeks of each other during the 4-year project time frame, and the remainder will receive both the RUSE and CRSP within 4 weeks of each other during the 4-year project time frame.

Preliminary Results—A total of 30 patients have been entered into the study. Eighteen patients have received CRSP, RUSE, and EXU, all within a 2-week period. Seven patients received RUSE and EXU within 4 weeks of both EXU and RUSE. A total of four patients who received RUSE and EXU within a 2-week period received CRSP more than 4 weeks prior to these. One patient underwent EXU and RUSE, and data for CRSP was unavailable due to technical problems. Divided by groups the totals are as follows: CRSP/RUSE within 2 weeks—18; CRSP/RUSE within 4 weeks—7; EXU/RUSE within 2 weeks—30.

There have been no formal reviews of the data collected to date. Twenty-three informal reviews have been done; however, there have been no conclusions drawn at this time.

Future Plans—Formal reviews will be done at the conclusion of the project.

[466] Enhancement of Neural Recovery in Spinal Injury: Utilization of Centrally Evoked Motor Potentials to Predict the Outcome of Early Kinematic-EMG Feedback Training and Functional Electrical Stimulation

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Purpose—The purpose of this project is to utilize centrally evoked motor potentials, along with other electrodiagnostic techniques, in the assessment of acute spinal injured patients and to determine the

relationship between these findings, motor recovery, and the response to a combined EMG-kinematic feedback training and electrical stimulation protocol.

Methodology—Electrodiagnostic procedures—electromyography (EMG), nerve stimulation studies, and magnetically evoked potentials—were performed with a Cadwell electrophysiological system (Quantum 84 and MES-10) on spinal cord injured (SCI) and non-SCI subjects. Disposable monopolar needles were used for all EMG studies and for recording evoked potentials when surface electrodes were inadequate (SCI subjects).

Measurement of muscle performance in SCI included peak knee-extension moment, fatigue resistance, work performed, and resistance to passive knee motion (5-230 degrees/second) with EMG recorded via intramuscular wire electrodes. Moment, position, velocity, and EMG from the isokinetic exercise device (LidoActive, Loredan Biomedical) were sampled by an IBM PC/AT. Treatment sessions were performed with the exercise device, and a visual feedback display guided volitional exercise, with electrical stimulation, according to the target programmed for moment, position, velocity, and/or EMG activity.

Preliminary Results—The results of this project to date indicate that it may be possible to estimate the origin of muscle weakness during the “wait and see” period after SCI. The origin of motor recovery after SCI may be attributed to return of function within the spinal cord, regeneration or axonal sprouting of peripheral nerve, or some combination of these mechanisms. Assessment of the first 35 incomplete SCI patients revealed a diversity of neurological findings, despite similar patterns of

motor weakness (i.e., Grade 2, or poor, quadriceps). Cervical injuries resulted, in some cases, in partial muscle denervation, with subsequent recovery associated with the formation of giant motor units. Low thoracic or lumbar injuries, whose weakness might be assumed to result from loss of anterior horn cells or peripheral nerve, also demonstrated diversity with a subgroup of patients appearing to have combined upper and lower motor neuron dysfunction. The presence of magnetically evoked potentials in the quadriceps (by scalp stimulation) has not preceded the discovery of volitional motor unit action potentials. The inability to centrally evoke motor potentials may, however, provide a means of detecting unsuspected perturbation of the spinal cord. Combined kinematic-EMG feedback training and electrical stimulation has resulted in improved knee extension performance for patients with adequate innervation of the quadriceps. Further analyses and comparison to the control subjects are in progress.

Recent Publications Resulting from This Research

Goal Setting in Spinal Cord Injury: Implications of Electrodiagnosis of Peripheral and Central Pathways (Abstract). Campbell JM et al., in Proceedings of the American Spinal Injury Association 7th Annual Conference, Orlando, FL, 121, 1990.

Kinematic-EMG Feedback Training and FES System For Spinal Cord Injured Patients. Meadows P et al., in Proceedings of the 13th Annual RESNA Conference, Washington, DC, 367-368, 1990.

Spasticity in SCI: Day-to-Day Variability in Response to Joint Movement and Electrical Stimulation. Campbell J et al., in Proceedings of the 14th Annual RESNA Conference, Kansas City, MO, 274-276, 1991.

[467] Standard Versus Low Molecular Weight Heparin in the Prevention of Thromboembolism in Spinal Cord Injury

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Purpose—The first phase of this study had as its objective to examine the safety and efficacy of low molecular weight heparin (LMWH) in the prevention of thromboembolism in patients with acute spinal cord injury and complete motor paralysis.

Progress—Our results showed that LMWH was significantly better than standard heparin with re-

spect to both thrombus prevention and safety.

As an ancillary investigation, we evaluated the effect of lower limb paralysis in the recanalization of deep vein thrombosis. Thirteen subjects with spinal cord injury took a mean of 54 days for recanalization as compared with 33 days for 26 nonparalyzed subjects; the difference between the two groups was significant at $p = 0.04$.

We are now attempting to determine whether 8 weeks of treatment with LMWH will be adequate to prevent thrombosis in patients with complete motor paralysis. Forty subjects have been entered into the current trial. Twenty-four have completed 8 weeks of treatment without thrombosis or bleeding. Twenty-one of the 24 were followed on no treatment for an additional 4 weeks and had weekly negative venous flow examinations. These subjects are considered to no longer be at risk for thrombosis. Three

completed the 8 weeks of treatment, but did not return for follow-up venous flow examinations.

Recent Publications Resulting from This Research

Prevention of Thromboembolism After Spinal Cord Injury Using Low-Molecular-Weight Heparin. Green D et al., *Ann Intern Med* 113:571-574, 1990.

Effect of Lower Limb Paralysis on the Recanalization of Deep Vein Thrombosis. Lim AC, Roth EJ, Green D, *Arch Phys Med Rehabil* (in press).

[468] Managing Urinary Tract Infection in Spinal Cord Injury

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Purpose—In this project we are investigating the techniques and procedures that will improve the prevention and treatment of urinary tract infection. Our objectives are to: 1) increase the patient involvement and responsibility in monitoring, prevention, and management of urinary tract infection; 2) develop a systematic approach in identifying the presence of infection, localizing the site of infection, and controlling the infection; and, 3) identify a safe management method for resistant bacteriuria.

Progress/Methodology—*Self-monitoring bacteriuria at home.* The Dip-Slide method used in this project to detect the presence or absence of bacteriuria appeared to be easy for the patients to learn and perform. Before discharge, patients were instructed in the procedure for using Dip-Slides, followed by an actual performance of the test and interpretation of the results by the patient. In this technique, the Dip-Slide with culture medium on each side is dipped into a fresh urine specimen, then placed in a warm location for 24 hours. The test results were incorporated into the bladder management at the first outpatient visit.

Forty-four patients participated in the study. Eight of the 44 patients did not perform the assigned testing at home. Approximately half of the patients studied indicated that the procedure was useful and that they would like to continue the test for self-monitoring. A quarter of the patients showed either no need or no interest to do this at home because they felt they had too many things to do

after discharge. Eleven patients still need to return the test reports at outpatient recheck. Eleven patients had significant bacteriuria and 16 had sterile urine culture detected by the Dip-Slide method.

Preliminary data suggest that the monitoring procedure can be incorporated as a part of the home program to increase the awareness of the problem and to initiate initial measures for bacteriuria before the patient's scheduled clinic visit.

Localizing the site of urinary infection prior to antibacterial therapy. In a previous study, we found that the Fairley Bladder Washout test could be simplified for use as a clinical screening procedure to localize the site of infection and sometimes achieve therapeutic results. The relationship between the site of infection and the method of treatment is being analyzed. So far, there still is difficulty in some cases in achieving complete bladder sterilization with the washout procedure. The possibility of determination of the site of urinary infection based on the total bacterial population rather than the bacterial concentration in the urine alone is being reviewed. The presence of increased white blood cells in the urine specimen may be an indicator for symptomatic bacteriuria (tissue invasion) even with the presence of low bacteriuric concentration (colonization).

Managing lower tract infection with resistant organisms. Six patients have been studied. All showed lower urinary tract infection with the modified bladder washout study. One patient showed conversion of the highly resistant organisms to

different yet sensitive organisms, while others showed elimination of the organisms from the urine following a 4-day course of intermittent catheterization and bladder irrigation. Sterile urine after initial bladder washout procedure was noted. The study appeared to indicate that repeated irrigation with diluted Betadine solution, then normal saline or saline alone, can convert the resistant organisms to

sensitive organisms or eliminate the bacteriuria completely. No noticeable side effects have been noted from the use of diluted Betadine solution, which is used in the bladder for less than a minute during the bladder irrigation. It is not clear yet as to the frequency and duration of Betadine irrigation needed to eliminate the bacteriuria.

[469] Expiratory Muscle Training in Spinal Cord Injury: A Randomized Controlled Clinical Trial

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Purpose—The proposed study has been designed to determine whether a simple expiratory muscle training program will be effective in improving expiratory force, increasing endurance, and reducing complications in individuals with spinal cord injury (SCI).

Methodology—Approximately 60 patients who have had a cervical or upper thoracic SCI no longer than 6 months prior to evaluation who meet study criteria are to be studied. At initial evaluation, the patient undergoes a comprehensive medical history, physical examination, and pulmonary function testing. Each patient is instructed in the proper use of an expiratory resistive breathing training device, through which the patient performs 10 expiratory maneuvers twice a day, for 30 days. Patients will be monitored by physician-investigators while performing the expiratory maneuvers. Patients will be assigned randomly into one of two groups: 1) the expiratory training group, which performs the program with a closed-end resistive breathing device; and, 2) the control group, which uses the device with an open gauge without respiratory resistance. At the end of 30 days of respiratory muscle training, each patient undergoes an exit evaluation of history, physical exam, and pulmonary function testing. The same procedure is performed at follow-up. Comparisons of results between training groups and between time periods is then conducted.

Preliminary Results—Preliminary data from the randomized controlled clinical trial of expiratory muscle training indicate that the technique is effective in improving four specific pulmonary function tests: forced vital capacity, forced expiratory reserve volume in 1 second, negative inspiratory force, and forced expiratory pressure. Most of the pulmonary function test results correlated with vital capacity in spinal cord injury patients. Expiratory muscle training was *not* effective in improving pulmonary function test results in healthy normal controls. In addition, four of the pulmonary function test results correlated with the level of spinal cord injury, but only one, expiratory reserve volume, correlated with the degree of spasticity.

Recent Publications Resulting from This Research

- Expiratory Muscle Training in Spinal Cord Injury: Preliminary Results (Abstract). Roth EJ et al., Arch Phys Med Rehabil 71:796-797, 1990.
- Pulmonary Function in Spinal Cord Injury: Effects of Weakness and Spasticity (Abstract). Roth EJ et al., Arch Phys Med Rehabil 71:788, 1990.
- Expiratory Muscle Training in Spinal Cord Injury: A Randomized Controlled Clinical Trial (Abstract). Roth EJ et al., J Am Paraplegia Soc 14:87, 1991.
- The Differential Effects of Weakness and Spasticity on Pulmonary Function in Spinal Cord Injury (Abstract). Roth EJ et al., J Am Paraplegia Soc 14:110, 1991.

[470] Treatment of Infertility Among Spinal Cord Injured Males Using Vibratory Stimulation

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Purpose—The objective of this project is to evaluate serial changes in hormonal levels, semen analysis findings, and clinical course using repeated vibratory stimulation of the penis in SCI men. By determining relationships between external stimulation, serial hormonal changes, and serial semen analysis results, this study is expected to provide new insights into mechanisms of infertility and their management in SCI patients.

Progress/Methodology—A total of 13 SCI males have been recruited and involved in this study. Of this group, 11 have had at least one successful stimulation attempt. In addition, retrograde (catheterized) specimens were obtained after each successful and unsuccessful stimulation attempt from each subject, including two patients for whom no antegrade specimen was obtained.

Semen and urine specimens are being analyzed

by the Andrology Laboratory of Northwestern Memorial Hospital. Data analysis is still in progress, and it is still too early to determine whether there are clinically or statistically significant trends in semen or sperm quantitative or qualitative factors with repeated serial stimulations.

In addition, some aspects of the stimulation itself are being studied during each stimulation session for each subject. These include: optimal placement location of the vibrator, duration of stimulation required for ejaculation, which vibrator type or whether alternative vibrator types will result in successful ejaculation, whether there is presence of erection during stimulation, and complications. Subject characteristics are also being documented, such as injury level and extent of injury, time since injury, medications, tone level, and whether there have been erections and/or ejaculations in the past since the injury.

[471] Effects of Prophylactic Aminophylline Administration on the Occurrence of Respiratory Insufficiency During the Acute Phase of Cervical Spinal Cord Injury

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Purpose—Maximal diaphragm function following acute spinal cord injury resulting in quadriplegia is vital for pulmonary well-being. Due to the added work required of the diaphragm following paralysis of the other muscles of respiration, any means to aid its function (i.e., improve its contractility and strength) would be beneficial to this patient population. It is the impression of many physicians that prophylactic administration of aminophylline improves diaphragmatic activity and respiratory function of patients with quadriplegia. Since pulmonary complications are the leading cause of death for persons with quadriplegia, the potential impact of a drug which improves respiratory function is enormous.

Therefore, a rigorous appraisal of the efficacy of this drug is warranted. The objectives of this study are to: 1) determine what dosage of aminophylline is necessary to achieve a therapeutic level through intravenous administration of the drug; 2) determine whether therapeutic levels of aminophylline can be maintained via oral administration of the drug after therapeutic levels have been achieved intravenously; 3) document the effect of aminophylline on parameters of pulmonary function including vital capacity, maximal inspiratory and expiratory pressures, 1-second forced expiratory volume, tidal volume, and arterial oxygen tension in persons who have recently sustained a lesion of the

cervical spinal cord; 4) document the effect on the above parameters of discontinuing aminophylline; and, 5) document the effect of aminophylline on diaphragmatic contractility in persons who have only recently sustained a lesion of the cervical spinal cord.

Progress/Methodology—First-year efforts include developing standardized data collection forms and accompanying syllabus, and identifying study subjects. Baseline arterial blood gas and pulmonary function data will be collected for all study patients at time of entry into the study. Aminophylline will then be administered intravenously to each study patient unless contraindicated by baseline tests. Serum aminophylline levels will be measured until a therapeutic level has been achieved. Factors that affect aminophylline tolerance and clearance will be

documented. The mode of aminophylline administration will be switched from intravenous to oral for all patients; serum levels will be measured at least twice after switching to oral administration to assure maintenance and stability of a therapeutic serum aminophylline level. When this level has been achieved and maintained, oral administration will be stopped. Pulmonary function data collected at appropriate times will be compared with baseline data to determine the effect of aminophylline administration for each patient. In this way, each patient will serve as his own control. In addition, the effect of aminophylline on diaphragmatic contractility will be documented. Two more 7-day trials of oral aminophylline administration will be conducted for each patient, with pulmonary function, diaphragm contractility, and blood gasses data collected at appropriate times.

[472] Psychosocial Adjustment of SCI Who Are Victims of Unintentional vs. Intentional Injuries

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Sponsor: *National Institute on Disability and Rehabilitation Research; Wayne State University; Rehabilitation Institute of Michigan*

Purpose—This research is part of a longitudinal study examining the adjustment of spinal cord injured (SCI) who are victims of intentional versus unintentional injuries. Studies of the effects of "Post-Traumatic Response," have not addressed the unique needs of SCI who are victims of violence.

The objectives of this proposal are to: 1) comprehensively review literature on theories of adjustment; 2) perform a psychometric evaluation of instruments that examine concepts from a model of adaptation (Meaning in Life Scale, Psychosocial Adjustment of Illness, Ways of Coping Checklist, Social Support Questionnaire, and Reintegration to Normal Living) with SCI who are victims of gunshot

wounds and are 3-5 years postinjury; and, 3) utilize focus groups to obtain adjustment data for SCI victims of intentional (gunshot, stabs, and assaults) versus unintentional (falls, accidents, and other diseases) injuries as well as nondisabled persons of similar age, race, and gender. Victims of violence are generally males, blacks, adolescents/young adults, separated or divorced, urban dwellers, and earning less than \$10,000; the demographics in the unintentional injury group is varied. The intent of this proposal is to identify the adjustment process of SCI and related theory so that rehabilitation nurses can increase the quality of life for SCI persons.

[473] Prophylaxis of Deep Vein Thrombosis in Acute Spinal Cord Injured Patients

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Purpose—Deep vein thrombosis (DVT) and pulmonary embolism (PE) represent a major hazard to patients with spinal cord injury (SCI). Reported incidence has ranged from 14% to 40% with clinical criteria, around 61% with impedance plethysmography or venography, and 70% to 100% with radio fibrinogen uptake tests. Chemical prophylaxis (with heparin, aspirin, etc.) has been found to be of limited efficacy, and is sometimes not used for fear of bleeding complications.

Another method of prophylaxis, the use of gradient elastic stockings, has not been systematically studied with this population to test its effectiveness in preventing DVT. The National Institutes of Health Consensus Development Conference suggested external pneumatic compression as the method of choice for prophylaxis in patients with SCI, but we have found only one study demonstrating its effectiveness in this population.

The purpose of this study is to determine the effectiveness of external pneumatic compression stockings alone and in combination with gradient elastic stockings in preventing DVT and PE in acute SCI patients.

Methodology—At least 96 consecutive patients with acute SCI admitted to the Detroit Receiving Hospital (DRH) SCI Unit will be randomized to one of four groups. Experimental Group #1 will receive the long leg gradient elastic stockings only. Experimental Group #2 will receive thigh-high intermittent pneumatic compression stockings only. Experimental Group #3 will receive both long leg gradient elastic stockings and thigh-high intermittent pneu-

matic compression stockings. The Control Group (#4) will receive no treatment.

These treatments will begin on admission to the SCI Unit at DRH and will continue after transfer to the Rehabilitation Institute of Michigan (RIM) for a total of 6 weeks, or until discharge from rehabilitation, whichever is less. After transfer to RIM, the pneumatic compression stockings will be worn only at night, so as not to interfere with the performance of therapies.

The 6-week time limit is based on the clinical observations that the majority of patients with acute SCI develop DVT in the first 30 days after injury. The patients will be evaluated using Duplex ultrasound on a weekly basis for 6 weeks. The noninvasive Duplex ultrasound procedure has been shown to be of excellent value in diagnosing DVT, when compared with radio fibrinogen uptake test and venography.

Progress—In order to determine the feasibility of implementation of the study, two patients were entered into a pilot study. The first patient received both the pneumatic compression stockings and the gradient elastic stockings. The second patient received the pneumatic compression stockings only. Neither of these patients developed deep vein thrombosis during the 6-week period they were involved in the study.

The first patient enrolled in the main study received the gradient elastic stockings only. This patient developed a DVT during the second week of the study. A second patient has been enrolled and is receiving the pneumatic compression stockings only.

[474] Histopathology of Denervated Skin Following Spinal Cord Injury

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Sponsor: National Institute on Disability and Rehabilitation Research

Purpose—Skin complications represent a leading source of morbidity in the spinal cord injured population, yet relatively little is known about the histopathology of denervated skin. In order to improve the clinical management of these complications, and ultimately to prevent them, we are conducting a study to increase the understanding of precisely what happens at the cellular and tissue level when the body's largest organ, the skin, is denervated.

The objectives of this study are to: 1) describe and establish the histopathology of denervated skin in patients with spinal cord injury (SCI) using appropriate laboratory and electron-microscopic techniques; 2) establish the pathogenesis and natural history of skin changes following SCI; 3) determine the nature of the relationship between the neurologic level and extent of SCI and the occurrence of specific skin changes; and, 4) determine whether there is a meaningful correlation between the severity of post-SCI skin complications and possible covariates such as the histopathologic changes observed, the neurologic level, and extent of lesion.

Methodology—Skin-punch biopsies are obtained from patients with SCI who have injuries that are neurologically complete, sensory sparing only, or motor nonfunctional. Study patients are divided

into three groups by level of injury: 1) T6 and above; 2) T7-T11 with sacral reflexes present and upper motor neuron evidence to legs; and, 3) T12 and below with absence of sacral reflexes and lower motor neuron loss to legs. Biopsy specimens are obtained from a group of patients who have chronic SCI, more than 1 year postinjury, as well as a prospective group of patients who were injured less than 2 months prior to the time the skin biopsy was obtained. Skin biopsies will be examined by a dermatopathologist using histopathologic methods of examination. In addition, a subset of the biopsies will be studied by electron microscopy.

Preliminary Results—The electron microscopy studies have been completed on 10 patients as outlined in the research methodology. There were no characteristic changes with the electron microscope that helped to determine the underlying defect in the skin collagen changes observed clinically.

Future Plans—Dermatohistopathology results were compiled and analyzed. Analysis includes comparison of the length of time after injury, the level of SCI, and changes observed in the prospective studies from year 1 to year 3. A final report of findings will be completed during the next year.

[475] Skin-CNS-Bladder Reflex Pathway for Micturition After Spinal Cord Injury

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Sponsor: Paralyzed Veterans of America, Spinal Cord Research Foundation

Purpose—The main goal of the project is to restore controllable voiding after spinal cord injury through the new reflex pathway, "skin-CNS-bladder"; namely, to allow the patients to initiate voiding by scratching the skin themselves. Since the results have

been so surprisingly and consistently good in the rat model, we strongly believe that the skin-CNS-bladder pathway may be applied to patients in a few years, after gradual testing of the pathway in higher animals and more detailed studies. Further study

will be carried out in cats (1991), dogs (1992), and monkeys (1993).

Methodology/Future Plans—The skin-CNS-bladder pathway will be established and tested in the animals on the same principles as in the rat. In addition, some important experiments will be done that are very difficult or impossible in smaller animals such as the rat. These include: 1) studying the response of

the external urethral sphincter to the skin-CNS-bladder reflex; 2) determining, as accurately as possible, the speed of axonal regeneration and the effect of nerve growth factor (NGF) on that speed; 3) determining where the regenerated axons terminate; and, (4) determining the most effective way to initiate the skin-CNS-bladder reflex voiding on conscious monkey models (i.e., by scratching, squeezing, or portable skin stimulator).

[476] Psychosocial Adjustment of Spinal Cord Injured Who Are Victims of Gunshot Wounds

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Sponsor: *Wayne State University*

Purpose/Methodology—This study is an examination of the adjustment of spinal cord injured (SCI) who are victims of gunshot wounds. Subjects selected will be less than 1 year and 1-3 years postinjury, and who are 12-26 years of age ($n = 50$). This study has three objectives, to: 1) examine the suitability of the Moos and Schaefer model; 2) conduct psychometric evaluations on constructs in the model: cognitive appraisal (Meaning in Life Scale), adaptive tasks (Psychosocial Adjustment to Illness Scale), coping skills (Ways of Coping Check-

list), and Outcome of the Crisis (Reintegration to Normal Living Scale). Norbeck's Social Support Questionnaire has been added to determine coping resources. The instruments will be administered in a semistructured interview format. The sites for data collection will be in an area which is mutually agreed upon between the client and the investigator; and, 3) compare selected personal factors of a sample of SCI from National Rehabilitation Hospital with a comparable data set from the Rehabilitation Institute of Michigan.

[477] Experimental Spinal Cord Injury: Effect of Normothermic Subarachnoid Perfusion in a Rat Model

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Sponsor: *None listed*

Purpose—Perfusion of the spinal subarachnoid space with hypothermic or normothermic saline has been reported as having a beneficial effect following spinal cord injury in monkey, cat, and dog. In recent years, the rat has been increasingly used as a model of spinal cord injury and has the advantage of enabling therapeutic trials with larger numbers. We report here an evaluation of normothermic perfusion of the spinal subarachnoid space in a contusion model of spinal cord injury in rats.

Methodology—A laminectomy (under general anesthesia) was carried out at T8, after which a 10-gm weight was dropped 5 cm. After injury, the laminectomy was extended to three levels, and the dura and arachnoid were opened. In the treatment group ($n = 10$), perfusion with normothermic saline (37°C) was carried out for 3 hours. The control group ($n = 10$) received no perfusion. The animals were followed for 28 days with sensory/motor

testing of hind-limb function at 3, 7, 14, 21, and 28 days.

Results—A multiway analysis of variance (ANOVA) compared the Combined Behavioral Score (CBS) in the treated and control groups at the five observation times. Both the perfused and control groups showed recovery of function over time ($p < 0.00000001$), but recovery of the perfused ani-

mals was significantly superior ($p = 0.033$). A similar analysis of the Tarlov motor component of the CBS revealed that the treated animals were superior ($p = 0.002$).

Implications—These data suggest that normothermic perfusion is of benefit in a rat model of spinal cord injury and that further study of this modality is warranted.

[478] Thyrotropin-Releasing Hormone (TRH) in Experimental Spinal Cord Injury

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Sponsor: None listed

Purpose—The purpose of this study was to examine the effects of thyrotropin-releasing hormone (TRH) in experimental spinal cord injury.

Methodology—Sprague-Dawley rats (body weight 200 to 225 gm) were subjected to a standardized contusion injury of the spinal cord under general anesthesia via laminectomy at T8. The injury consisted of a 10-gm weight dropped from a height of 5 cm. The animals were randomly assigned to either a nontreatment control group ($n = 10$) or to a TRH treatment group ($n = 10$). TRH was administered intravenously via a cannula in the internal jugular vein: 2 mg/kg bolus followed by 2 mg/kg/hr continuously for 4 hours. Behavioral testing for

sensory/motor recovery was carried out at intervals over the course of 4 weeks, after which the animals were sacrificed.

Results—There were no statistically significant differences in recovery of function between the TRH-treated and the control group. Pathologically, morphometric analysis of the residual gray and white matter of the spinal cords showed that there were likewise no statistically significant differences between the treated and control groups. In this model, TRH was not found to be of benefit in preserving spinal cord function or in maintaining the integrity of spinal cord tissue.

C. Spinal Cord Regeneration

[479] Axonal Regeneration in Artificial Nerve Graft Model

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Sponsor: VA Rehabilitation Research and Development Service (Project #B387-2RA)

Purpose—Indications for nerve grafting vary from gaps of 1 cm to greater than 5 cm or more before a graft would replace an end-to-end repair under

tension. Where a graft is indicated autografts are the preferred method at the present time. The autograft fulfills three major requirements for an ideal nerve

graft: 1) it acts as a passive conduit for axonal regeneration; 2) it is a natural substitute that is immunologically acceptable; and, 3) it is vascularized by the recipient bed as a free graft. The major limitation of the autografts is the requirement of a donor nerve. Homografts and heterografts have been evaluated as an alternative to autografts but have been found to be immunologically unacceptable. Therefore, the development of an artificial nerve graft is necessary to solve both problems of availability and rejection by the immune system.

The purpose of this study is to examine the regeneration of the peripheral nervous system through an artificial nerve graft composed of a synthetic conduit of collagen and fibrin filled with a collagen Type I matrix.

Methodology—In this study five non-human primate subjects were used to compare different types of nerve repairs. The first repair used biodegradable collagen/fibrin ANGs filled with a collagen Type I matrix. The second repair used the same collagen/fibrin ANGs without a collagen growth matrix. The third type of repair used sutured autografts. Nerve segments 30 mm long were removed from the dorsal branch of the ulnar nerve and the palmar cutaneous branch of the median nerve and the dorsal branch of the radial in both arms of the monkeys. The type of repair at each nerve was randomized so that each type of nerve would be repaired by each type of graft.

[480] Improved Function After Electrical Stimulation of Injured Spinal Cord

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Sponsor: VA Rehabilitation Research and Development Service (Project #B423-2RA)

Purpose—The application of electrical fields has been shown to direct nerve cell growth in tissue culture and also enhance recovery in spinalized animals. The present study was conducted to determine if the application of a pulsed electrical field to the injured cat spinal cord could result in an improved functional recovery as measured by electrophysiological, behavioral, and anatomical techniques.

Progress—After the nerves were allowed to regenerate for 11 months, the animals were sacrificed and preliminary qualitative histological evaluations were made. Not all of the experimental nerves showed complete regeneration, but the results are promising. Nerves grew a partial distance through the tubes before ending in a neuroma formation. Tubes containing a collagen Type I growth matrix grew further. We are now beginning to quantitatively analyze the histological data.

Implications—The results of this study should provide us with direction toward fabricating an ideal artificial nerve graft before proceeding to clinical trials. We believe that by using different materials with slower degradation rates to fabricate the tubes, they will last longer and guide the nerve to their distal targets. The release of growth factors by these new ANGs, we believe, will also enhance nerve regeneration.

Recent Publications Resulting from This Research

Artificial Nerve Graft Using Collagen as an Extracellular Matrix for Nerve Repair Compared to Sutured Autograft in a Rat Model. Rosen, et al., *Ann Plast Surg* 25(5):375-87, 1990.

Comparison of Nerve Repair Techniques: Suture vs. Avitene-Polyglycolic Acid Tube. Pham, et al., *J Reconstr Microsurg* 7(2):1991.

Artificial Peripheral Nerve Grafts with Collagen Matrix: Comparison of Polyglycolic Acid and Glycolide Trimethylene Carbonate Resorbable Tubes. Rosen, et al., *J Biomed Mater Res* (in press).

Methodology—Eight cats weighing 2-2.5kg were anesthetized with an intramuscular injection of ketamine and xylazine. A laminectomy was performed at T8-T10 and the spinal cord was subjected to a contusion injury at the T9 level using a modified weight drop method which delivers an impact force of 75 to 85N to the spinal cord. These animals received daily postoperative care in accordance with American Association of Accreditation of

Laboratory Animal Care (AAALC) guidelines. Of these eight cats, four received platinum disc electrodes which were inserted 2cm above and below the level of the lesion and connected to an implantable pulse stimulator.

The cathode and anode were placed caudally and rostrally, respectively, to the injury site. The electrodes were placed epidurally with the anode on the dorsal surface and the cathode on the ventral surface of the spinal cord. The electrical stimulation consisted of 20 μ A peak current of 0.5msec duration with a frequency of 10Hz.

For 6 to 7 months, the animals were examined for behavioral performances using a wide range of tests. Somatosensory and spinal evoked responses were recorded monthly. Bladder function was assessed by weekly Crede procedure (suprapubic pressure) for voiding. At the end of the 6-month experimental period, all animals were anesthetized and multiple injections of WGA-HRP were given at the lower cervical spinal cord in order to assess the sparing or regrowth of injured spinal fibers.

Preliminary Results—One of the four unstimulated cats was capable of limited ambulation, pushing with the dorsum of its hindpaws while keeping its knees close to the ground. The second cat appeared to be voluntarily pushing slightly with its hindlimb. None of the cats in the nonstimulated group showed

any tactile placing responses or any weight bearing in the hindlimb.

Electrophysiological recordings showed the absence of somatosensory and spinal evoked responses in all animals after trauma following stimulation of the tibial nerve. However, in the stimulated cat showing the most behavioral recovery, responses were present at 120 days post-trauma while absent at 60 and 90 days post-trauma.

All animals remained continent of urine during our 10-week study and required four or five Crede procedures (suprapubic pressure) for voiding. By the third week, the bladders of the stimulated animals could be easily emptied with Crede applied once or twice. High urethral resistance following spinal injury makes it difficult to empty the bladder. Improved voiding associated with spinal cord stimulation may indicate inhibition of the urethral sphincter.

WGA-HRP labeled cells and processes were found across the lesion site in 50% of both stimulated and surgical control animals. Labeling was more extensive and more intense in the spinal cords of animals implanted with stimulators.

Future Plans—Further studies are planned using controlled electrical stimulation methods as well as objective assessment techniques to determine whether or not there is a clear functional benefit of applied electric fields in spinal cord injury.

[481] Axonal Regrowth Across Transected Rat Sciatic Nerve Implanted with Carbon Filament Prostheses

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Sponsor: VA Rehabilitation Research and Development Center (Core Funds)

Purpose—Current methods of peripheral nerve repair often result in unsatisfactory restoration of function. In some situations, a significant loss of nerve tissue may result in a gap too wide for end-to-end anastomosis. In this case, a nerve graft is necessary to bridge the gap. Although a nerve autograft would be the preferred method of repair, problems occur with obtaining donor nerve. An

alternative is to use an artificial nerve graft as abridge. In our laboratory, it has been shown that small diameter carbon filaments can support and give directionality to growing rat fetal spinal cord explants. We have also shown that carbon filaments implanted into the transected adult rat spinal cord can promote axonal growth across the transection site. In the present study, we evaluated the feasibility

ity of using carbon filament implants in the repair of peripheral nerve.

Methodology—Young adult rats were anesthetized and the left sciatic nerve was cut. The proximal and distal ends were inserted into the ends of a silicone tube containing approximately 10,000 carbon filaments (5 μ m diameter) 5 mm in length. The nerve stumps were held in place with a small amount of cyanoacrylate adhesive applied between the epineurium and the tubing. The right sciatic nerve served as a control. After 60 days, the rats were anesthetized and both the left and right sciatic nerves were crushed distal to the injury. WGA-HRP (0.3 μ l of a 2% solution) was injected into crushed distal of each nerve. After 24 hours, the animals were sacrificed and perfused. The spinal cords were removed, fixed, sectioned, reacted for WGA-HRP, and segments L2-S5 were observed for labeled cells.

[482] Feasibility of Carbon Filament Prostheses to Induce Spinal Cord Regeneration

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Sponsor: VA Rehabilitation Research and Development Center (Core Funds); Paralyzed Veterans of America

Purpose—Our recent studies have demonstrated that small diameter carbon filaments (5 μ m in diameter) give support and directionality to growing neurites *in vitro*. This observation was further confirmed by our *in vivo* study, as we observed axons 2–3 mm below a spinal cord transection site which was previously filled with carbon filaments.

The present study was conducted to determine whether axons observed growing across a carbon fiber implant were capable of transmitting somatosensory evoked potentials (SSEPs) across a transection site.

Methodology—Thirty 200g rats sustained total spinal cord transection at the T8–T9 level. In 18 of these animals, the resulting transection gap was filled with a 5mm-long bundle of approximately 10,000 carbon filaments of 5 μ m diameter. Nine rats served as surgical controls. Three rats, in which the transection gap was filled with ordinary cotton, served as substrate controls.

Preliminary Results—Labeled cells were found on the left half (injury side) of the spinal cord. Numerous labeled cells were always seen on the right (control side) of the spinal cord. These early studies suggest that carbon filament implants are capable of supporting axonal regrowth in peripheral nerve.

Future Plans—Further studies are planned to study the functional recovery after the carbon filament implants. In addition, carbon filament implants in combination with other growth promoting agents and their effect on functional recovery will be assessed.

Recent Publications Resulting from This Research

Carbon Filament Implants Support Axonal Regrowth Across Transected Rat Sciatic Nerve. Sayers S, Dauzvardis M, Khan T, Neurosci Abstr 17:565, 1991.

Noninvasive SSEPs were elicited by applying a constant current anodal stimuli to the distal tail. SSEPs were recorded at the proximal tail, lumbar-sacral spine junction, thoracic spine (T9) and cervical spine (C6–7) at 1-week intervals. After a 6 to 8-week survival period, a final SSEP was recorded and the animals were studied histologically.

Results—No SSEPs were recorded at any time across the transection site in the regular controls and the cotton controls. Fifty percent of the animals implanted with carbon filaments showed thoracic responses 4 to 6-weeks postlesion and 80% of these showed at 6 to 8-weeks postlesion. One in three of carbon implanted animals showed cervical responses after 6 weeks postlesion. These preliminary results indicate that a carbon filament prostheses may prove useful in encouraging the regrowth of injured spinal cord axons.

Future Plans—We are planning to study carbon filament implants in combination with other growth promoting agents in order to achieve the optimal regrowth of injured axons resulting in functional recovery.

Recent Publications Resulting from This Research

Carbon Filament Implants Promote Axonal Growth Across the Transected Rat Spinal Cord. Khan T, Dauzvardis M, Sayers S, *Brain Res* 541:139-145, 1991.

Culture of Rat Fetal Spinal Cord Explants on Carbon Filaments. Khan T, et al., *Neurosci Lett* 100:172-176, 1990.

[483] Comparison of Fetal Cerebral Cortex Versus Fetal Spinal Cord Tissue for Transplantation

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Sponsor: *American Paralysis Association*

Purpose—The purpose of this study is to compare fetal cerebral cortex with fetal spinal cord tissue for transplantation in spinal cord injured rats.

Methodology—Young adult Sprague-Dawley rats (190-220 gm) were subjected to either mild (10-gm weight-drop from 2.5-cm height) or moderate (10-gm weight-drop from 5-cm height) spinal cord contusion injury and were then implanted with either fetal day-16 cerebral cortex or fetal day-14 spinal cord tissue. Transplantation was performed in separate groups (n=3 per group) of animals immediately following trauma and at 1, 3, 7, 14, 21, and 28 days postinjury; injured control animals were injected with saline only. After allowing 14 days for growth of the transplant, rats were sacrificed and their spinal cords were examined histologically by qualitative and quantitative methods.

Results—Virtually all cerebral cortex implants grew successfully, completely filling the injury defect with a solid, cohesive mass of mature-appearing gray

matter. Neuropil from cerebral-cortex transplants blended imperceptibly with residual host spinal cord gray matter. Cerebral cortex implants incorporated well at all postinjury intervals. Fetal spinal cord tissue implants were less successful, failing to survive in over half of cases; when incorporated, they did not fill the injury defect, resulting in significant syrinx formation. Implants with spinal cord tissue were associated with negative histopathological sequelae, including meningeal proliferation, mesenchymal metaplasia, choroid plexus proliferation, continuing chronic inflammation, and poor mesh between transplant and residual host tissue.

Implications—The findings suggest the superiority of fetal cerebral cortex transplants and provide evidence that growth is not inhibited by the traumatized cord environment. Furthermore, postinjury effects such as hemorrhage, necrosis, and gliosis may not be as detrimental to implant survival as previously thought.

[484] Control of Muscle Atrophy in Spinal Cord Injury

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Sponsor: *Eastern Paralyzed Veterans Association*

Purpose—The overall goal of this project is to explore the use of B2-receptor agonists to retard muscle fiber atrophy due to disuse. These studies are an outgrowth of our work on the control of muscle protein turnover by calcium, cAMP, and passive

tension, since B-receptor agonists may act by altering calcium and cAMP pools. Recently, we found that clenbuterol, a selective B2-receptor agonist, causes muscle growth that is mostly due to hypertrophy of fast-twitch muscle fibers. Other

experiments showed that B2-agonist treatment retards disuse atrophy of both slow- and fast-twitch fibers. In addition, contractile strength of slow- and fast-twitch muscles is increased.

Methodology—We will examine in detail the ability of clenbuterol or terbutaline to retard muscle fiber atrophy due to denervation or cordotomy in rats. Muscles will be examined with respect to fiber type area, twitch and tetanus tension, fatigability, electromyographic activity, and myosin isoforms. Because the degree of muscle usage is an important variable in B2-agonist stimulated muscle growth, muscle responses to a combination of electrical stimulation and clenbuterol will be tested. In addition,

changes in protein synthesis, proteolysis, releasable myofilaments, cAMP and insulin binding will be measured in atrophying muscles after *in vivo* or *in vitro* treatment with B2-agonists to give some insight on the responsible cellular mechanisms. The ability of butoxamine or propranolol to block the effects of clenbuterol will be determined.

Implications—Optimization of B2-agonist treatment of muscle atrophy due to denervation or cordotomy may lead to a useful therapeutic modality for the treatment of muscle atrophy resulting from prolonged bed rest, immobilization, certain neuromuscular diseases, and spinal cord injury.

[485] Molecules Affecting Axon Growth in the Central Nervous System

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Sponsor: Paralyzed Veterans of America, Spinal Cord Research Foundation

Purpose—This study seeks to identify and characterize molecules which stimulate and direct the growth of axons in the developing central nervous system (CNS). The aim is to define the molecular properties unique to these axons.

Methodology—Antigens will be chemically screened to determine if they are unique to developing nervous tissue, and biological assays will be performed to determine their ability to affect axon growth.

Progress—Forty monoclonal antibodies have been developed that appear to recognize antigens present in developing CNS and absent or nearly absent in adult CNS; a second screening process will be performed.

Preliminary Results—A new *in vitro* bioassay methodology has been perfected which solved previous technical limitations with the preparation, that is, the staining and attachment of cryosections. Significant growth preferences of CNS and PNS neurites for various substrates have been observed. Data have also suggested that defined growth factors may effect the substrate preference of axons.

Future Plans/Implications—The aim of this research is to provide a greater understanding of molecular factors that favor CNS recovery. Learning to control the molecular environment of CNS injury may lead to the means to promote recovery.

[486] Neurochemical Alterations Following Spinal Deafferentation

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Sponsor: *Paralyzed Veterans of America, Spinal Cord Research Foundation*

Purpose—The purpose of this project is to understand the neurochemical and morphological events which contribute to the reorganization of the spinal gray matter following injury. The project is intended to benefit the development of therapeutic approaches. Specifically, the objectives are to determine the changes in immunostaining patterns in the dorsal horn which occur approximately 1 week, 3 weeks, and 4 to 6 months after deafferentation. The investigation is part of an overall effort to observe the response of target neurons to the loss of a portion of their afferents and the possible sprouting of noninjured primary afferents.

Methodology—Experimental rats are prepared with pronase injections. Spinal cord nuclei are sectioned, stained for peptides normally found in primary afferents, and mounted on slides for analysis using a computerized densitometry analysis system. Several types of statistical analysis are applied to the data.

Progress—Analysis has been completed for the peptide CGRP, and image analysis is in progress for the remaining three peptides (SP, CCK, and SS). Immunostaining is being optimized for a fifth peptide, VIP. All the appropriate methodology for analysis has been determined using the CGRP data.

Preliminary Results—Preliminary analysis of CGRP data indicates a very significant loss of CGRP after pronase injection. Visual inspection of the immunostaining of the other peptides also indicates decreases.

Future Plans/Implications—The indication from the data that there may be a partial recovery after several months will now be examined by comparing short- and long-term effects. Possible rearrangement of neurochemicals will be examined to determine their synaptic organization and source using electron microscopy and double labeling techniques.

[487] Effects of Fetal Central Nervous System Transplants on Locomotion Function in the Chronically Spinal Cord Injured Cat

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Sponsor: *Paralyzed Veterans of America, Spinal Cord Research Foundation; American Paralysis Association; Cincinnati VA Medical Center*

Purpose—The primary goal of this project is to determine whether transplanting fetal neural tissue into the chronically injured spinal cord can lead to functional improvement. This includes two aims: 1) to test for functional improvements in locomotor function after fetal spinal cord or brainstem tissue grafts; and, 2) to determine if removal or rejection of transplanted tissue eliminates those improvements.

Methodology—The fetal tissue is transplanted to the site of spinal cord injury; in some sites, the grafts are later removed, either surgically or by immune

reaction. Locomotor function will be evaluated and magnetic resonance imaging will be used to examine grafts.

Progress—The project is in early stages of evaluating locomotor function after injury and implantation of transplant.

Future Plans/Implications—Approaches to placing donor tissue into the injured site by injections of prepared central nervous system tissue are still under consideration.

[488] Physiologic Mechanisms of Spinal Cord Plasticity

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Purpose—Spinal cord injury causes immediate loss of function below the site of damage, followed by gradual recovery of variable degree and time course. The long-term changes in spinal function reflect the spinal cord's great capacity for plasticity. This plasticity is thought to take many forms, including modification of the efficacy or the organization of synaptic connections. Experimental studies of spinal cord plasticity are usually performed in surgically lesioned or mechanically traumatized animal preparations. Identification of the basic mechanisms of plasticity is difficult in such models because of the diffuse (and often massive) alterations of supraspinal influences, complications from the secondary effects of injury (e.g., altered spinal cord blood flow, edema, humoral effects) and the complexity of the ensuing plastic changes which these alterations elicit.

Studies from this laboratory have demonstrated operant conditioning of the two-neuron arc of the spinal stretch reflex, the simplest and most accessible pathway in the primate central nervous system, and have shown that this conditioning causes plastic changes in the spinal cord. These changes remain even if the spinal cord is separated from supraspinal influences. Thus, this approach provides a novel model for studying spinal cord plasticity in response to a discrete perturbation of a simple reflex pathway. Available data suggest that the most probable sites of spinal cord plasticity in response to reflex conditioning are the Ia afferent-alpha motoneurons

in the ventral horn. Thus, to test the hypothesis that conditioning changes the alpha motoneuron or the Ia afferent, we will study animals in which the triceps surae H reflex amplitude in one leg has been increased or decreased by chronic operant conditioning.

Methodology—Animals will be deeply anesthetized, placed in a spinal frame, and surgically prepared. We will characterize triceps surae motoneurons on the basis of their intrinsic properties. We will characterize afferent mechanisms by measuring the effects on the motoneuron of stimulation of directly projecting afferent nerves. We will then compare the data from motoneurons on the conditioned and the control sides of the spinal cord to determine whether plastic changes are evident in the motoneuron and/or in the afferent connections to them. Study of triceps surae motoneuron responses to other synaptic inputs and study of non-triceps surae motoneurons will delineate the distribution and specificity of these modifications.

Implications—This work will localize and define the plastic changes produced in the spinal cord by operant conditioning and should begin to reveal the mechanisms that create them. In concert with anatomic studies, it will prepare the way for pharmacologic, biochemical, and ultrastructural investigation of spinal cord plasticity.

[489] Neurochemical Alterations Following Spinal Deafferentation

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Sponsor: Paralyzed Veterans of America, Spinal Cord Research Foundation

Purpose—We have developed a spinal cord model of plasticity evoked by primary deafferentation. We wished to study the effects of making a very

selective lesion of just one system that contributes to spinal circuitry. We chose the primary sensory fibers that enter the spinal cord by way of the dorsal roots.

Our model is based on selective destruction of the dorsal root ganglion cells (primary sensory neurons) which arise from the sciatic nerve in the hindlimb.

In the adult animal, simple cutting of the sciatic nerve does not destroy very many of these cells, and their processes which enter the spinal cord usually survive. However, we have developed a method to kill these cells by injecting the nerve with proteolytic enzymes (pronase). One week after injection, the synaptic terminals of these nerve fibers in the spinal dorsal horn die, indicating that an effective lesion has been made. Within 3 weeks, there is atrophy of the dendritic processes of the dorsal horn neurons and loss of terminals from other sources that contact these dying dendrites. We have also observed this secondary degeneration after dorsal root cutting and after nerve cutting. This finding indicates that the reorganization which occurs also must take into account partial loss of target structures, as well as the original loss. Finally, we have demonstrated a third stage which is fully evident 4 months after the pronase injection. By injecting tracers (WGA-HRP and bCT-HRP) into the nearby saphenous nerve (which innervates another area of the hindlimb), we found that the terminals of the saphenous nerve in the dorsal horn had spread (sprouted) into part of the area that had been occupied previously by the sciatic nerve terminals. In addition, the new synaptic terminals each contacted more dorsal horn dendrites than normal. We now propose to continue the study of these findings by determining if there are parallel changes in the neurochemistry of the dorsal horn that can be attributed to the structural changes we observe.

Several studies of other investigators have found many neurochemical changes that accompany either dorsal root cutting or nerve cutting. In some cases certain neurochemicals decrease with the injury and are later partially or totally restored. These

changes may also reflect sprouting or other types of reorganization. There are several unique advantages to conducting similar studies in our model: 1) these neurochemical changes can be studied in a model in which the morphological events can also be defined; 2) we have the prior experience to study several different neurochemicals in the same animals; and, 3) we will study the changes at both the light microscope and electron microscope level.

Methodology—We will first determine the neurochemical organization that occurs at each of the three states in which we have observed changes. That is, we will inject the sciatic nerve of rats and wait either 1 week, 3 weeks, or 4 months. At these times we will then sacrifice the animal and immunostain the spinal tissue for each neurochemical in adjacent tissue sections. We hypothesize that after 1 week there will be a loss of those neurochemicals associated with sensory nerves; that after 3 weeks there may be additional losses associated with the death of dorsal horn dendritic processes and their attached synaptic terminals; and that after 4 months there may be partial restoration and possible rearrangement of the neurochemicals that may in part be due to afferent sprouting.

Implications—If these changes are observed at 4 months, we will conduct further experiments to determine if the saphenous nerve is indeed one source of these immunochemicals and to determine their synaptic organization using electron microscopy and double labeling techniques.

These studies are intended to understand the neurochemical and morphological events that occur following spinal injury, as these are critical to the determination of the potential for functional recovery.

[490] Mechanisms of Action of Substratum Bound Macromolecules in Promoting Axonal Growth

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Sponsor: *Paralyzed Veterans of America, Spinal Cord Research Foundation*

Purpose—Growing neurons send out long, thin extensions called axons. At the tip of the axon is the growth cone. The growth cone is made up of a broad, flat expansion called the lamellipodium, from which extend finger-like filopodia. During nerve cell development and regeneration, the growth cone explores the environment and guides the axon to make contact with appropriate target cells. Important cellular substances contained in structures called organelles travel to the end of the axon along intracellular "railroad tracks" called microtubules. The microtubules and organelles stop at the end of the axon (at the central region of the growth cone). The lamellipodium and filopodia are free of organelles and are rich in the cytoskeletal fibers called actin filaments. Outside the nerve cell lies the extracellular matrix and intricate meshwork of molecules that support nerve cells and influence their development and function. It was previously believed that the adult central nervous system cells, including spinal cord nerve cells, could not regenerate after injury. However, it has been found that the axons of nerve cells can be stimulated to grow by molecules of the extracellular matrix, particularly the protein laminin. Little is known about how extracellular matrix molecules actually stimulate axonal growth. We are interested in determining the molecular mechanisms by which extracellular matrix molecules stimulate axon growth and the changes that occur in the growth cone to allow this growth.

Progress/Methodology—We have been using high-resolution video microscopy to observe growth cones in living nerve cells. Video microscopy is a recently developed technique that allows one to observe organelles, lamellipodia, and filopodia in living nerve cells with a clarity and resolution that

had previously not been possible using the conventional techniques of light microscopy. We have been observing axon growth in giant nerve cells from the sea slug, *Aplysia californica*, a widely used animal research model for studies of nerve cell function. When nerve cells are grown on tissue culture dishes, extracellular matrix molecules stimulate axon growth only when bound to the dish (the substratum) in a manner similar to the way these molecules stimulate axon growth in animals or humans. We were surprised to find that a substratum-bound factor from the blood of *Aplysia* stimulates *Aplysia* axons to grow by rapidly promoting the forward movement of organelles from the axon into the organelle-free area of the lamellipodium. It has been thought that extracellular matrix molecules help stimulate axon growth just by providing a sticky surface for the axons to grow on. The results with *Aplysia* have led us to wonder whether extracellular matrix molecules in vertebrate animals also stimulate axon growth by rapidly stimulating the forward movement of organelles. Previous studies have not addressed, with the resolution possible with video microscopy, the changes that occur in vertebrate growth cones when neurons are stimulated to grow by extracellular matrix molecules, and the molecular mechanisms that underlie the growth stimulation. Using video microscopy, we wish to further explore how the substratum-bound factor of *Aplysia* stimulates axon growth and how extracellular matrix molecules such as laminin work in vertebrate nerve cells to stimulate axon growth.

Recent Publications Resulting from This Research

- Rapid Effects of Laminin Neurons. Rivas RJ, Goldberg DJ, J Cell Biol 111:49a, 1990.
Rapid Laminin-Induced Changes in Sympathetic Growth Cones. Burmeister DW, et al., Soc Neurosci Abstr (in press).

[491] Electrophysiological Studies of Dorsal Horn Neurons Rostral to the Spinal Cord Hemisection in Awake, Drug-Free Animals

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Sponsor: Paralyzed Veterans of America, Spinal Cord Research Foundation

Purpose—Chronic pain has been reported in 10-33 percent of spinal cord injury (SCI) patients and is frequently resistant to many conventional pain treatments. While many causes of the chronic pain have been offered, recent animal studies, including work from our laboratory, demonstrate significant modifiability of spinal cord sensory neurons and suggest that SCI may permanently change the way the central nervous system interprets information, resulting in some signals being perceived as painful. Based on these studies and other human neurosurgical reports, we hypothesize that in the spinal cord, adjacent to injured segments, changes occur in the way that neurons respond to normal stimulation. We further hypothesize that these changes are likely to be responsible for some forms of chronic pain in SCI patients.

Methodology—Our laboratory has recently developed a technique to study spinal cord physiology in intact, awake, drug-free animals, and thus this study is unique in that we will be examining neural activity as it occurs normally. In addition, because we are able to conduct experiments over many weeks in the same animal, we will be able to observe time-dependent changes in sensory processing. Thus, we

propose, first, to test the feasibility of our technique to study the sensory processing capabilities of spinal dorsal horn neurons above a specific spinal cord lesion (hemisection) in otherwise intact, awake, drug-free animals. We propose next to study short- and long-term changes in neuronal responses immediately above the hemisection. And finally, we propose to initiate studies of pharmacological means to return sensory processings toward normal.

Future Plans/Implications—We expect to observe some types of abnormal responses to hindlimb skin stimulation (natural noxious and non-noxious stimulation) in some spinal dorsal horn neurons. We also expect to see increased levels of spontaneous activity. Since these changes may reflect a mechanism for the production of pain following spinal cord damage and are likely to be due to altered neurochemical modulation of spinal sensory processing, these pilot studies will lead to further studies of the physiology and pharmacology of such changes, with the intent of defining the pharmacology that can restore normal sensory processing or eliminate abnormal activity that could generate inappropriate pain messages.

[492] Evaluation of Methylprednisolone versus Tirilized Treatment of Rat Spinal Cord Injury

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Sponsor: Paralyzed Veterans of America, Spinal Cord Research Foundation

Purpose—Methylprednisolone (MP) has recently been shown to be effective in improving the outcome of spinal cord injured patients when administered within 8 hours of spinal cord injury (SCI). Promising preliminary results with Tirilized (U74006F) have also been reported. However, several treatment factors require further investigation.

For example, preliminary data in our laboratories using the rat SCI model have suggested that the efficacy of Tirilized, in particular, may be dependent on the severity of injury, and the optimum window of administration for either drug has not yet been firmly established. Some data suggest that Tirilized may be relatively more efficacious than MP

when delivered later after the time of injury. Although MP is being used prophylactically for neurosurgery in some hospitals, its efficacy has not been ascertained. Finally, the mechanism of action of MP is not fully understood. Although it has been suggested that it acts to inhibit lipid peroxidation, under some conditions MP has been shown to be more efficacious than other, more potent lipid peroxidation inhibitors, including Tirilizad. The following experiments are proposed to resolve these issues.

Methodology—First, the functional outcome of rats receiving one of three grades of SCI (mild, moderate, or severe) will be evaluated using two behavioral tests of locomotor and postural function, two descending motor function tests (auditory startle responses (ASR) and cerebellar motor evoked potentials (CMMEP) and somatosensory evoked potentials (SEP)). Rats will be treated either with MP or Tirilizad (using doses determined efficacious from previous studies) for 48 hours beginning 1 hour

before injury or 3 or 4 hours after injury. The animals will be evaluated at 2, 7, 14, and 21 days postinjury. The data will be analyzed statistically to determine the relative efficacy of MP versus Tirilizad as a function of injury severity and time of treatment onset. Second, neurophysiological correlates of functional recovery will be studied in acute experiments at 3 weeks postinjury. Axonal conduction at the site of injury will be evaluated by measuring conduction velocity of ascending and descending tracts, and axonal conduction as a function of stimulus frequency. Changes in the responsiveness of hind-limb motoneurons below the level of injury to peripheral and descending supraspinal inputs will also be evaluated by testing the interaction of these inputs using myoelectric recordings and intracellular motoneuron recordings. These data should help elucidate the mechanisms of functional recovery following spinal cord injury, with particular regard to the site of action (injury region or segmental) of MP and Tirilizad.

[493] Changes in Axonal Conduction and Neuronal Excitability Following Spinal Cord Injury in the Rat

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Sponsor: *Paralyzed Veterans of America, Spinal Cord Research Foundation*

Purpose—Previous studies have shown that various means of peripheral stimulation can enhance motor responses to descending and peripheral inputs in chronically injured humans or animals. In particular, we have shown that the drug 4-aminopyridine (4-AP), which can enhance both axonal conduction and synaptic transmission, improves motor responses to descending signals in chronically injured cats. These studies are highly relevant to the treatment of chronic spinal cord injury, since they suggest that many patients may have intact descending tract fibers that are for some reason incapable of carrying out motor commands. We propose to extend these studies to determine the relative contribution of enhancement of axonal conduction through the injury region and increased responsiveness of motoneurons to descending and peripheral inputs.

Methodology—These studies will be carried out in a newly developed rat model of spinal cord injury. They will involve electrophysiological recording of axonal and neuronal responses in the spinal cord to brainstem and peripheral nerve stimulation. These experiments will elucidate the physiological basis for the enhancement by 4-AP of motor function. Motor responsiveness during the acute and chronic recovery period will be studied using a neurophysiological test (auditory startle reflexes) to evaluate the effectiveness of descending reticulospinal pathways, and a behavioral test (modified inclined plane test) to evaluate function of the postural support system.

Recent Publications Resulting from This Research

Effects of Anesthetics on Somatosensory and Motor Evoked Potentials in Rats. Gruner JA, Sieczka EM, presented at the 1990 Society of Neurotrauma, St. Louis, MO, 1990.

Long Term Recovery of Sensory-Motor Function After Spinal Cord Contusion in the Rat. Gruner JA, Levine N, presented at the 1990 Society of Neuroscience Meeting, St. Louis, MO, 1990.

Assessment of Functional Recovery After Spinal Cord Injury in Rats by Reticulospinal-Mediated Motor Evoked Responses.

Gruner JA, Kersun JM, Electroencephalogr & Clin Neurophysiol (in press).

Role of Synapsin I and Cam Kinase II in the Regulation of Transmitter Release in the Squid Giant Synapse. Llinas R et al., J Neurophysiol (in press).

[494] Mechanism of Action of Neuritogenic Gangliosides in Central Nervous System Regeneration

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Sponsor: *Paralyzed Veterans of America, Spinal Cord Research Foundation*

Purpose/Methodology—The inability of central nervous system (CNS) neurons to regenerate after injury continues to be a mystery with overwhelming neurological consequences. Although CNS neurons are clearly able to grow when the organism develops, it is not understood why this ability is lost at maturity; we lack understanding of the process that regulates the ability of the axon to grow over a substrate and then to correctly identify its appropriate partner. We believe that if several factors are involved, merely recapitulating some of them during regeneration will not be sufficient to cause functional recovery. Even though presenting injured CNS neurons with grafts will permit them to

elongate over large distances, the grafts do not also stimulate the formation of connections between the injured neurons and their targets.

We aim to investigate the process of target finding by determining how growing neurons behave toward particular cues that cause the pathfinding response. To do this we have isolated the area of the neuron responsible for pathfinding (the growth cone) from the axon itself so that we are able to study these molecular interactions in isolation. We believe that only when we understand the regulation of every process involved in axonal growth will we be able to successfully design strategies to allow injured CNS neurons to regenerate.

XVI. Wheelchairs and Powered Vehicles

A. General

[495] Curvilinear Synchronous Motors for Wheelchairs

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Sponsor: VA Rehabilitation Research and Development Service (Project #B338-2RA)

Purpose—The purpose of this project is to use a synchronous permanent magnet motor for the wheelchair drive mechanism. The drive will supplant all transmission belts and gearing; two motors will act as direct drive on each of the two rear wheels.

Progress—Considerable progress has been made on the design of the motors themselves; a multitude of designs have been explored using computer models.

Methodology—By proper choice of both the air gap geometry and magnet orientation, we have been able to simulate motors which are capable of producing more torque than competing 3-phase designs using the same magnets and excitation current. Such improvements constitute quite an advantage to long-term performance and efficiency over alternative designs. Patent applications prevent the detailing of many of these innovations. A second innovation behind this project is the manner of controlling

the motor. Because the motors are direct drive, it is necessary to control position and speed by the current excitation. Utilization of the CUK circuit offers several advantages in terms of the voltage supply necessary to run the motor. Using inductors, capacitors, and a switching thyristor, the CUK circuit acts as a DC-DC voltage converter. This allows control of the speed of the motor irrespective of the back EMF of the motor (and thus the speed), within the limits of the actual CUK amplification. This greatly expands the range of speed control realizable from two 12-volt batteries.

Results—We are now in the testing stage of the computer models. Upon completion of these tests a motor with controller will be mounted on a wheelchair for testing in place. It appears that we will greatly enhance the efficiency, and thus the range, of the electrically driven wheelchair.

[496] SCI Responses to Wheelchair Propulsion During Fatigue: A Pilot Study

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Sponsor: Rehabilitation Research and Development Service (Project #B90-87AP)

Purpose—The overall goal of this 1-year pilot project is to evaluate objectively how the physical characteristics of nonathletic spinal cord injured (SCI) wheelchair users relate to upper-extremity

stresses, and how wheelchair propulsion biomechanics change with fatigue during wheelchair locomotion.

Progress—Upon completion of 6 months of this 1-year project, a total of 11 male paraplegic subjects have participated. Software for the calculation of joint moments and joint reaction forces at the shoulder, elbow, and wrist is in the final stages of development.

Methodology—Twenty male paraplegics (age 18–40 years with spinal cord lesions between T5 and L5) will be recruited for this investigation. All subjects will undergo medical screening to eliminate those with contraindications to exercise. Body measurements, muscle strength, and neuromuscular assessments will be performed for each individual. A wheelchair instrumented with strain gauges for measuring handrim force will be positioned on stationary rollers for data collection. Five channels of electromyography will be used to document upper-extremity muscle patterns. Movement will be videotaped using a three-dimensional motion analysis system, and heart rate and oxygen uptake (VO_2) will be monitored during each data collection session. Subjects will perform two wheelchair roller exercise tests. One test will be a graded continuous exercise test for determination of peak physiologic responses. The second test will be a fatigue test consisting of exercise for 6 minutes at 30% peak VO_2 with incremental workload increases until volitional fatigue is achieved.

All data will be collected and analyzed using a 386 IBM-compatible computer. Shoulder, elbow,

and wrist joint kinetics (joint moments and joint reaction forces) will be calculated from the motion and handrim force data. A correlational analysis will be performed to determine which physical characteristics are related to upper-extremity joint moments and joint reaction forces. Pre- and post-fatigue kinematic and kinetic measurements will also be compared using a multivariate analysis of variance with repeated measures.

Preliminary Results—Average age of subjects who have participated in the study thus far is 33 years (maximum 64, minimum 24.5 years) and average time since injury is 9.6 years (maximum 18.6, minimum 1.0 years). All participants are paraplegic, with injury levels ranging from T₅ to T₁₂. The system developed for acquisition and analysis of wheelchair propulsion data appears to provide the multidisciplinary approach desired for analysis of wheelchair propulsion.

Future Plans/Implications—Determination of physical characteristics which are related to high joint stresses and identification of biomechanical factors which change with fatigue provides the necessary foundation for optimizing wheelchair function. These findings may be applied to decreasing injuries in SCI wheelchair users by improving propulsion techniques, wheelchair design/prescription, and therapeutic intervention.

Recent Publications Resulting from This Research

Multidisciplinary Data Acquisition and Analysis of Wheelchair Ergometry. Kobayashi M, et al., in Proceedings of the 13th International Congress on Biomechanics, Perth, Australia, 1991.

[497] Development of Standards for Transportable Mobility Aids

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Sponsor: Canadian Standards Association

Purpose—The purpose of this work is to ensure that disabled persons can obtain mobility aids that are suitable for transportation. Currently, we are working on three Canadian Standards Association (CSA) subcommittees on: "Transportable Mobility Aids"

(Z604), "Securement Systems" (Z605), and "Transportation Vehicles for Disabled Persons" (D409). The work in Ottawa is being performed in association with Biokinetics and Associates, Ltd., and also with TES, Ltd., two companies involved in the

design and construction of devices for physically disabled persons, as well as in transport safety research.

Methodology—The work includes a contract from CSA to design and construct a "surrogate" wheelchair to be used in a dynamic testing program for wheelchair securement and restraint systems. The essential goal of the CSA is to establish standards

for securement systems and for mobility aids which will ensure safer transport for disabled persons.

Progress/Future Plans—The work on this contract is proceeding satisfactorily and is scheduled for completion during the coming year. Research will proceed on the transportation of persons with physical disabilities.

[498] Use of the Levo Chair in the Management of Multiple Sclerosis and Spinal Cord Injury Patients

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Sponsor: *Eastern Paralyzed Veterans Association*

Purpose—This project seeks to determine the benefit of a "standing wheelchair," the Levo chair, in the management of patients with paraplegia or quadriplegia due to multiple sclerosis or spinal cord injury. Patients in the study will assume the upright position in the Levo chair for a half-hour, twice

daily. The effects of passive standing on cardiovascular fitness, musculoskeletal tone, bone metabolism, genito-urinary function, skin integrity, and psychologic status will be assessed at monthly intervals before, during, and after treatment.

[499] Behavior of Manual Wheelchairs Under Different Loads

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Sponsor: *Innovative Research Programme for the Disabled*

Purpose—The object of the project is to determine the critical loads for a wheelchair during daily use and during test situations. The second aim is to develop tools for designers and manufacturers for stress and load analyzing.

Methodology—The forces on the footplate, the seat, and the back, and the acceleration at the wheel axis, are measured in different situations with a specially instrumented standard wheelchair. Finite element models (FEM) for three different types of wheelchairs are developed. Stress analyzing has been performed by using the MSC-PAL2 program of the Mac-Neal Schwendler Cooperation. The results of

the force measurements are used as an indicator for the external load on the models. The FEM results are verified by measurements on a modern wheelchair equipped with strain gauges. Dynamic simulation models of wheelchairs are developed, using the multi-body program BAMMS and the MADYMO program.

Progress—For each of the FEM models, four different load cases were analyzed. In all these circumstances, the stress remained within the allowable stresses. Special attention is paid to fatigue of wheelchairs. The load situation during a fatigue test on the TNO-belt machine is compared with the load

of different use situations, in order to create a load envelope. Rough comparison of the dynamic simulation results with the fatigue test shows reasonable resemblance. By parameter variation of the model, the influence of some wheelchair characteristics will be investigated. This may facilitate the development of the load envelope.

[500] Ergonomics of Manual Wheelchair Propulsion

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Sponsor: *Innovative Research Programme/Aids for the Handicapped*

Purpose—Manual wheelchair propulsion is being studied for a number of years with a combined physiological and biomechanical perspective. The general aim is to improve the mobility of wheelchair users, as far as the wheelchair is concerned. Important areas of research are factors influencing the work capacity and power output of the wheelchair user as the "motor" in wheelchair mobility; factors influencing wheelchair-user interaction both in terms of biomechanics and physiology.

Methodology—Wheelchair propulsion is being studied during wheelchair exercise tests on a motor-driven treadmill and during simulated conditions on a computer controlled wheelchair ergometer. During the treadmill tests (studies on prototype evaluation; performance capacity; propulsion technique) physiology is combined with kinematics (3-D) and electromyography. On the wheelchair ergometer, a 3-D reconstruction of the movement pattern of arms and trunk is combined with measures of force and power production as well as with electromyography of upper arm and trunk muscles and overall physiology. An inverse dynamics segment model is used to interpret cardiorespiratory phenomena and measures of efficiency from a biomechanical and anatomical perspective.

Progress—Studies have been initiated into the effectiveness of torque production under various conditions of power output, such as (sub-) maximal aerobic tests and sprint tests, and in different groups of disabled and nondisabled subjects. A group of 68

Recent Publications Resulting from This Research

Modelling the Mechanical Behaviour of Wheelchairs with Finite Element Methods. Zonneveld R, in *Wheelchairs Testing in Europe*, 109-115, R Ronchi, R Andrich (Eds.). Milan: Comac-BME, 1990.

Strength and Durability of Manual Wheelchairs. Pauwelussen JP, in *Wheelchairs Testing in Europe*, 79-86, R Ronchi, R Andrich (Eds.). Milan: Comac-BME, 1990.

wheelchair athletes were studied during the 1990 World Games for the Disabled in Assen, both on the track and during standardized tests on the ergometer.

Lever propulsion was studied both in one-arm and two-arm propulsion with respect to the cardiorespiratory load and propulsion technique. The validity of the ergometer was evaluated in a comparison of exercise tests on the treadmill and the ergometer.

Future Plans—An extensive experiment evaluating the effects of variation in geometry of the wheelchair-user interface (seat height, width, camber, rim diameter, fore/aft position) will be conducted on the ergometer. An in-depth analysis of the hand during the push phase of hand-rim wheelchair propulsion will be conducted on the ergometer in conjunction with close-up movement analysis.

Recent Publications Resulting from This Research

A Computer Controlled Wheelchair Ergometer. Niesing R, et al., *Med Biol Eng Comp* 28:329-338, 1990.

Direction of Propulsive Forces in Manual Wheelchair Propulsion. Veeger HEJ, van der Woude LHV, Rozendal RH, in *Proceedings of ECART*, Maastricht, The Netherlands, 1990.

Fitting the Wheelchair to the Man? An Outline of a Research Methodology. van der Woude LHV, Veeger HEJ, in *Wheelchairs Testing in Europe*, R Rochie, R Andrich (Eds.), 97-107. Milan: COMAC-BME, 1990.

Physiological Evaluation of a Newly Designed Lever Propulsion Mechanism. van der Woude LHV, Veeger HEJ, in *Proceedings of ECART*, Maastricht, The Netherlands, 1990.

Seat Height in Hand Rim Wheelchair Propulsion: A Follow-up Study. van der Woude LHV, Veeger HEJ, *J Rehabil Sci* 3:79-83, 1990.

Within-Cycle Characteristics of the Wheelchair Push in Sprinting on a Wheelchair Ergometer. Veeger HEJ, van der Woude LHV, Rozendal RH, *Med Sci Sports Exerc* 23(2):264-271, 1990.

Inertia and Muscle Contraction Parameters for Musculoskeletal Modelling of the Shoulder Mechanism. Veeger HEJ, et al., *J Biomech* 24(7):615-629, 1991.

Load on the Upper Extremity in Manual Wheelchair Propulsion. Veeger HEJ, van der Woude LHV, Rozendal RH, *J Electromyogr Kinesiol* (in press).

Peak Oxygen Uptake and Maximal Power Output Responses of Olympic Wheelchair Dependent Athletes. Veeger HEJ, et al., *Med Sci Sports Exerc* (in press).

[501] Battery Technology Research

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Sponsor: *Labatt's Blue Light Relay*

Purpose—The objective of this project is to give a wheelchair user the maximum service life from his wheelchair battery. One of the risks in charging batteries unattended is the danger of overcharging them. Similarly, undercharging is detrimental and can shorten the service life of a battery.

Methodology/Progress—A prototype of a control

box that will monitor the state of the battery at all times is under development. It will be connected between the charger and the batteries and will prevent overcharging. When the charger is disconnected, the control box will give the user current information on the state of the battery. The control box will be ready for testing during the coming year.

[502] Wheelchair Evaluation and Standards Development

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Sponsor: *Ministry of Health of Ontario*

Purpose—The purpose of this project is to test mobility devices for the Assistive Devices Branch of the Ministry of Health of Ontario prior to their acceptance for funding.

Methodology—The equipment used to test wheelchairs includes the following: 1) electric timing devices; 2) an accelerometer; 3) energy consumption measurement equipment designed specifically for powered mobility products; 4) a fully variable-angle ramp with powered control of angle; 5) a digital readout of slope; 6) a table capable of measuring rotation through a complete 360°; 7) a set of ISO test dummies; and, 8) a complete set of curb heights.

Progress—Minimal acceptance criteria for wheelchairs were established, and an expansion was made to our testing protocol to cover nonstandard wheelchairs and wheelchair power add-ons. Evaluations were also performed this year on special tilt/recline systems. This involved development of a new test protocol and review of the acceptance criteria to bring them in line with the different type of testing. Recently, we have begun to test power add-ons for manual wheelchairs.

Future Plans—We plan to expand the testing to cover other devices.

[503] Evaluation of Wheelchair Tiedowns Using Simulated Automobile Crash Testing

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Sponsor: National Institute on Disability and Rehabilitation Research

Purpose—There are an increasing number of companies manufacturing and selling wheelchair tiedowns for use in the transportation of disabled passengers. The objective of this research is to evaluate the effectiveness of those tiedowns in a crash situation.

Methodology—The major focus of the research will be on the use of wheelchair tiedowns in passenger cars and vans. There will, however, be some testing of tiedowns designed for use in public transportation. The University of Virginia Automotive Safety Laboratory uses a crash sled to simulate collisions. The sled impacts a barrier, and depending on the stiffness of that barrier, produces a deceleration pulse. The pulse can be tailored to simulate that of different automobiles in different crash situations.

A variety of popular manual and powered wheelchairs will be used in the testing. The chairs are secured to the sled using the tiedowns, and an instrumented dummy is placed in the seat. The dummy is secured by a variety of lap and shoulder belts. The tiedowns, dummies, seatbelts, and wheelchairs are instrumented to gather force and acceleration data. The data is used for computer simulations. In addition to instrumenting the setup, high-speed photography is used to record the events.

Progress—The testing is in its early stages. To date, several tests have been run on both driver and passenger-type tiedowns with varied results. Most of the tiedown failures were due to faulty buckles or tearing of belts. There have been several tiedown models that have worked well in 20g frontal crashes.

[504] Care-Free Wheelchair Tire

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Sponsor: National Institute on Disability and Rehabilitation Research

Purpose—The design of a maintenance-free wheelchair tire and the development necessary to see that the tire reaches the marketplace began in 1988.

Progress—The results of this effort are beginning to come to fruition this year. The new tire is non-pneumatic with a finite-element designed structure that is unaffected by punctures. It has all the characteristics of typical pneumatic tires in rider comfort, rolling resistance, compression set, skid marking, and weight. In addition, it has better abrasion resistance and coefficient of friction than a typical pneumatic wheelchair tire, and has the major

advantage of being flat-free. The tire is essentially a wheelchair lifetime tire.

The initial design work was done in England at the Malaysian Rubber Laboratory, and the first tires to reach the marketplace are to be manufactured there. These tires are to be marketed by REMPLOY Wheelchair Division, Sheffield. In the United States, the manufacture of the tire is being developed by Cadillac Rubber and Plastics, and it is estimated that sample tires for evaluation will be available in the near future from the University of Virginia Rehabilitation Engineering Center.

[505] Research and Development of Assessing Wheelchair Lifts**John G. Thacker, PhD**

University of Virginia Rehabilitation Engineering Center, Charlottesville, VA 22903

Sponsor: National Institute on Disability and Rehabilitation Research

Purpose—The University of Virginia Rehabilitation Engineering Center (REC) for Personal Licensed Transportation for Disabled Persons was established to provide improved technology with potential to provide benefit to more than 250,000 Americans who would be best served with vans for their personal transportation needs. To this end, a list of absolute priorities was published in the April 25, 1989 *Federal Register*. The first priority was to evaluate and test existing vehicle modification devices and equipment. These tests and evaluations are to be consistent with any standards and/or specifications of existing DOT and SAE standards for adaptive devices. The SAE has for the past several years established committees to set standards on these vehicle modification devices for the physically challenged. The SAE committee on wheelchair lifts has developed a new standard for the performance of wheelchair lifts that are used with vans. The University of Virginia will aid this committee's efforts in the evaluation phase of the standard.

Progress—A test device has been constructed that

will subject a wheelchair lift to static and dynamic loads. A hydraulic cylinder is used to provide the high static loads, and an 8088 personal computer equipped with data acquisition and control relays will be used to cycle the lift under load for the prescribed number of cycles. Limit switches will be used for the sensors, and a thermocouple will monitor the motor temperature. A 200 amp 50 mv shunt will monitor motor current. A 12-volt 125 amp DC power supply will provide the electrical power to drive the lifts. Five lifts will be evaluated, four platform lifts, and one rotary lift. The platform lifts will include track and parallelogram lifting frames driven by both hydraulic/electric and electromechanical devices. At the end of the evaluations, recommendations will be made to the SAE committee on problems encountered and clarifications that need to be made. Several lift manufacturers have been very helpful in aiding the REC by donating lifts for evaluation and providing equipment and background knowledge to aid in the evaluation of the standard.

[506] Research and Development on Assessing Wheelchair Ride Comfort**John G. Thacker, PhD; James J. Kauzlarich, PhD**

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Sponsor: National Institute on Disability and Rehabilitation Research

Purpose—As wheelchair designs and wheelchair-related equipment evolve, a method is needed to evaluate the effect of these changes on ride quality and comfort. The development of different seating systems, wheels and tires, and frame designs will affect ride quality. Quantitative assessment is needed to provide users with meaningful and useful information.

Progress/Methodology—A speed-measuring system has been designed to determine the instantaneous

speed of the wheelchair for level floor tests over control obstacles. The data processing computer routines have also been upgraded to improve the efficiency. The test method has been shown to be sensitive to tire types and obstacle heights, and is reproducible using the treadmill test platform. Typical data collection for manual and powered wheelchairs will be continued.

Manual wheelchairs have been tested at five different speeds (0.69 m/s, 0.97 m/s, 1.25 m/s, 1.53 m/s, and 1.80 m/s), and three different obstacles

(flat, 6 mm rod, and 16 mm rod). All acceleration standard deviation results are at least an order of magnitude less than the average. Hence, one test will give a representative indication of the ride quality based on the ISO standard, ISO 2631-1978E, *Guide for the Evaluation of Human Exposure to Whole-Body Vibration*. The weighted rms acceleration value may be compared to the magnitudes published in the Standard to determine whether the ride is comfortable for the time period under examination. For example, if the time period under examination is 4 hours, and vertical vibrations are being considered, the weighted rms accelerations should be less than 0.168 m/s^2 for the ride to be considered comfortable. For the same time period, if one were interested in what vertical acceleration levels could be allowed before a person's proficiency at performing a task would be reduced (fatigue), the value is 0.53 m/s^2 . The other boundary is the exposure limit (i.e., the maximum acceleration levels one could be exposed to without health risks). For the above example, the exposure limit is 1.06 m/s^2 .

The ISO Standard 2631-1978 also gives the maximum limits for accelerations in particular frequency bands. The lowest level of acceleration

tolerated occurs in the frequency band between 4 and 8 Hz. The maximum acceleration in this frequency band for the wheelchair traversing the obstacles has also been measured for manual wheelchairs.

Future Plans—This work will be continued. More treadmill data will be collected for powered wheelchairs. Accelerations will be studied and comfort level sensitivities will be recorded using the ISO Standard on Rider Comfort. As discovered in previous work, the ISO wheelchair test dummy will not give reliable results when evaluating accelerations for comfort. Hence, able-bodied human subjects will be subjected to the comfort test. Also, if available, the new maintenance-free tire will be evaluated.

A standard manual wheelchair and a standard powered wheelchair will be used in the study. Both wheelchairs will be tethered on the treadmill and subjected to various height obstacles at various speeds. The powered chair will have the drive belts removed and the batteries will be replaced with comparable weights.

[507] Research On Improving Wheelchair Frame Durability

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Sponsor: National Institute on Disability and Rehabilitation Research

Purpose—When confronted with the task of designing the structure of a wheelchair for use in a fatigue environment, the designer must find a method to establish the fatigue performance of the material to be used and, based on the knowledge of the loading characteristics, estimate whether the structure or component will survive over a specified design life. This design process is complicated by two facts: 1) most of our knowledge of fatigue of metals is composed of experimental observations and empirical correlations and has very little theoretical framework in which to base the analysis; and, 2) in the general case, every parameter involved in the fatigue estimation problem is stochastic in nature, suggesting a probabilistic treatment of the analysis. With the recent emphasis on probabilistic analyses in

structural mechanics, the random fatigue problem is particularly suited for investigation because the phenomenon is random at its very basis.

Progress—The work accomplished this past year developed a methodology for estimating the reliability of a wheelchair structural component in a random fatigue environment, i.e., estimating the probability of survival of a wheelchair component acted upon by randomly varying loads, causing a randomly varying state of stress that is severe enough to lead to fatigue failures. The calculation procedure developed uses the simplest fatigue model available, the classical high cycle region S-N curve, and the Palmgren-Miner Ratio Summation theory (Miner's rule), and assumes that the stress history of

the structure is adequately described by a stationary, narrow-band Gaussian random process. The random nature of the material's ultimate strength and the static stress acting throughout the structure are accounted for, and the result is a closed-form statement for the probability density function of cycles to failure. Using input data that should be readily available for most designs, the proposed computation allows the designer to make estimates

of the reliability of a structure or component and to assess the relative merits of one design over another with respect to reliability. Because this method acknowledges the random nature of some of the design parameters, it should give a more accurate picture of the performance of the wheelchair over the design lifetime than a purely deterministic analysis.

[508] Disability and Need Among Wheelchair Users

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Sponsor: Scottish Home and Health Department

Purpose—A number of studies have examined the problems faced by people with wheelchairs. They looked at samples of wheelchair users and showed that their problems with respect to wheelchairs and wheelchair service is part of a general lack of awareness of aids, benefits, and services.

No study appears to have been carried out on people who have recently been provided with wheelchairs, and yet it is these people who could reasonably be expected to have problems with coordination of delivery of services. It was proposed, therefore, to look at the "unmet needs" of people in the community who have recently been provided with wheelchairs. Their unmet needs for equipment, benefits, and services were examined, comparing them with an unmatched sample of existing wheelchair users. "Unmet needs" were those which could be ameliorated by intervention of an appropriate available service which was acceptable to the individual.

Methodology—A prospective study was carried out on a random sample of 50 people who had a wheelchair for less than 3 months. An unmatched group of 50 longer term wheelchair users, who had a wheelchair for more than 1 year, was also randomly selected. Data were collected by means of a questionnaire. The questionnaire provided a structured framework for the interview and a standardized method of recording data. All interviews were conducted by the researcher.

The questionnaire was designed to provide

quantitative data about the patient's diagnosis, environment, and need for services and allowances. Information regarding the suitability of the patient's wheelchair was also recorded.

Progress/Final Results—The data collection is now complete. The mean age of participants in the recent group was higher than that of the established group. A higher proportion of the recent group was aged 65 years or over. This result was in line with general demographic trends. Given the older age group, more people in the recent group were widowed; therefore, a higher proportion were living alone or in an institution.

There were distinct differences between groups in the type of wheelchairs provided. In the established group, only 28% of patients had attendant-propelled chairs. The remainder had self-propelled chairs, indicating a higher level of independence. Conversely, a high level of dependence was indicated in the recent group, as 62% of patients had attendant-propelled chairs. There was evidence, therefore, that the established group required their wheelchairs as their primary means of mobility. Some patients in each group expressed difficulty in using their wheelchairs both indoors and outdoors. These difficulties were closely linked to environmental factors.

There were unmet needs for services in both groups. A higher number of people in the recent group were receiving physiotherapy. Community occupational therapy was the service that was

received by most people. There was a general lack of awareness of which professionals were actively involved with the patient. District nurses and home helps seemed to be the services that could be most clearly identified by individual patients. This is, perhaps, understandable as they are the services that offer tangible, practical help, usually on a frequent basis. The need consistently identified by both groups was a need for equipment.

A chi-square test was carried out to ascertain whether the need for equipment, benefits, and

services was significantly different between the two groups. There was a trend for the recent group to have a greater need for benefits, rather than there being a statistically significant difference.

Future Plans—The researcher is currently producing an information booklet that will be available to all people to whom wheelchairs are issued. The booklet will contain information on how to obtain appropriate benefits, equipment, and services.

[509] Determination of Optimum Wheel Configurations for Wheelchair Users

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Sponsor: *Scottish Home and Health Department*

Purpose—Significant numbers of wheelchair users have only marginal ability to propel themselves independently. Their propelling abilities can be enhanced considerably by optimizing the configuration and positioning of the wheels of their wheelchair. This project is intended to determine the influence of wheelchair wheel adjustments and variations on the propelling abilities of marginal users.

Methodology—A highly adjustable wheelchair simulator will be developed to permit variations in wheel types configuration and position. A range of mar-

ginal users will propel the wheelchair simulator through a series of standardized maneuvers. Their performance for the different simulator adjustments will be quantified by overall test measurements and analyzed by video recording and propelling force measurements.

The results will be interpreted to give guidelines on optimizing wheel configurations for patient characteristics.

Progress—Funding has been approved to conduct this project: it commenced in November 1991.

[510] Wheelchair Tie-down System for Mainline Buses

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Sponsor: *Urban Mass Transportation Administration; National Easter Seal Society*

Purpose—Although an increasing amount of public transportation is "wheelchair accessible," there is no universal, easily applied system for safely securing a wheel chair while in transit. This project is aimed at developing an improved securement system for use on mass transit buses.

Methodology—This project consists of four phases. The initial phase was to evaluate tie-down systems currently in use and to specify where improvements are needed. This was accomplished through surveys, industrial contacts, and sled impact testing. The second phase is to design and construct prototype systems which implement the improvements speci-

fied in phase I. Phase III will consist of testing the prototype systems. This will include static and dynamic bench testing, sled impact testing with various types of mobility devices, functional testing by consumers, and finally, a field trial with wheelchair users on mainline buses in service. The final phase of the project will be a thorough training program for users and, most importantly, mass transit personnel.

Results—Phase I is complete and has shown that improvements are needed in order for a system to be user-operable, universal, and rapidly applied. Phase

II is in progress with three design concepts. The most promising of these is currently being constructed.

Implications—A convenient securement system will be utilized more often, providing safer transportation, increased accessibility, and reduced frustration for disabled and able-bodied passengers. A successful securement system on mass transit buses would naturally be adopted by other forms of transportation, including personal automobiles, school buses, airlines, trains, and rapid transit systems.

[511] Environmental Requirements for the Wheelchair User

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Sponsor: Federal Ministry for Regional Planning, Building and Urban Development

Purpose—The purpose of the basic research, which started before 1975, was to define the individual ergonomic requirements for users with different wheelchairs and to define the spectrum of action in relation to space used. The goal had been to find a way of generalizing space requirements by the highest possible percentile of all available and used mobility aids on wheels. The goal was set furthermore to develop a matter of applying this type to meet ergonomic requirements without independent or particular knowledge about the type of wheelchairs used or the individual disability.

The first cross-referenced comparison of the moving patterns of various wheelchair models was undertaken by the Institute T.L.P.e.V (Society) in 1971. At that time, 16 different types and makes of hand-propelled wheelchairs were entered into the study, which was conducted as a simulation in a room with 10×10 cm pattern flooring and recorded by a camera arrangement from the ceiling. The wheelchairs were operated only in part by disabled persons.

The first results suggested a solution that on the other hand seemed not possible, because the individual dimensions of the various wheelchairs used, including all important values such as f.e. width, seat height, length, curving behavior and center of gravity varied greatly. A definition of a mean value

rate for all seemed impossible. Other factors making a solution improbable were the different behavior, anthropometric, and asymmetrical handling patterns caused and influenced by different disabilities and affected by the age of the individual wheelchair user.

In 1978, the Institute T.L.P.e.V (Society) decided to begin long-term research on a large scale with the original goal in mind, but including the parameters of all persons using wheelchairs and including an evaluation of persons using other than wheelchair mobility aids.

Methodology—The first simulated object-approaching experiments were renewed, including some 280 persons with different disabilities of all ages using various wheelchairs, including electric-powered wheelchairs. The results were compressed into a set of space frames individually relating to all major objects for use in housing and public buildings. Frames were built to apply to toilets, bathtubs, sinks, doors, aisles, etc. Applying these basic space frames for planning, the Institute offered cost-free consulting and advice to any home builder and to construction of any type of public building as well as special-purpose rehabilitation, hospital, or special care buildings. This service was performed in the

national campaign to become "barrier-free for all people."

In cases where answers to certain problems could not be rendered with the minimum-frames developed, the given situation would be simulated in the laboratory and a solution would be found. Projects that had received advice were visited 6 months after completion. Critical and insufficient conditions were analyzed and, if necessary, simulated in the laboratory to correct the basic minimum-frame system.

Progress—This service has been active for 12 years. During that time more than 3,500 buildings of all kinds have been evaluated, involving some 9,000 disabled users, since over 65 projects were disabled housing or special care and rehabilitation institutional projects, housing in each case 10 or more disabled persons.

B. Powered Controllers

[512] The NavChair Control System for Automatic Assistive Wheelchair Navigation

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Purpose—Several projects within the University of Michigan Mobile Robotics Laboratory have developed and employed navigation methods for autonomous mobile robots which include high-speed obstacle detection and avoidance systems. The purpose of this new research study is to transfer this navigation technology from a mobile robotic platform to a commercially available powered wheelchair. The goal of this computerized supervisor is to help a user with marginal or insufficient motor capabilities for operation of standard wheelchair controls to safely and effectively use a powered mobility system.

The assistive wheelchair navigation system under development, called NavChair, will use ultrasonic obstacle feedback to construct a real-time map of surrounding environmental obstacles. The wheelchair operator control inputs will then be reviewed and edited to ensure obstacle avoidance while matching the operator-prescribed speed and directions to the greatest extent possible. For individuals unable to effectively steer a wheelchair straight due to tremor, visual impairment, or other disability, the NavChair will also optionally provide the ability to

follow along a wall at a constant safe distance, while ignoring small changes in direction resulting from motor or sensory impairment.

Methodology—An array of 8 to 12 Polaroid ultrasonic sensors will be mounted around an Everest & Jennings Lancer wheelchair. These sensors will be controlled by a portable 80486-based navigation computer mounted on the chair. A second source of sensor information will come from wheel position sensors which are already incorporated in the Lancer wheelchair. Standard wheelchair control inputs will be intercepted by the navigation computer. This arrangement will allow the computer to read wheelchair control commands from the user and then alter them when necessary, based on environmental obstacle data assembled with the sensor array. The sonar array will operate continuously to maintain a two-dimensional map of obstacles detected around the wheelchair. The grid map information will be reduced to safe steering and motion commands in real time, using fast data reduction techniques developed for mobile robots.

Results—The first months of this project have been devoted to modifications of the Lancer wheelchair as well as the robot navigation routines. All necessary wheelchair control signals have been intercepted and brought out for connection to the navigation computer. Sensor mounting and testing are beginning. The robot navigation routines have been altered to operate in totally unknown environments and with a differential rear wheel drive (as opposed to the three wheel synchronous steering drive use in previous robotics applications).

Future Plans—Work in the next year will center on completing construction of the modified wheelchair and porting navigation software from its current robot version to the new wheelchair version. By the end of the first year, we expect to have the

NavChair system operating at a rudimentary level. Year two will focus on testing and optimization of the sensor array and navigation algorithms within the laboratory environment. Year three will entail operation testing in real world environments and modifications based the results of this testing.

Recent Publications Resulting from This Research

The NavChair Control System for Automatic Assistive Wheelchair Navigation. Levine SP, Borenstein J, Koren Y, in Proceedings of the 13th Annual RESNA Conference, Washington, DC, 193-194, 1990.

The NavChair System—A New Concept in Intelligent Wheelchair Control. Borenstein J, Levine SP, Koren Y, in Proceedings of the Fifth Annual Conference on Technology and Persons with Disabilities, California State University at Northridge, 1990.

[513] Eye Wink Control Interface: A Pilot Study

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Sponsor: VA Rehabilitation Research and Development Service (Project #C89-51AP)

Purpose—The intent of the Eye Wink Control Interface (EWCI) project is to free persons with high-level quadriplegia from the restrictions on their speaking, head positioning, and movement and/or gaze direction during the act of controlling motorized wheelchairs.

Progress—We have established the components, protocols, and efficacy of the EWCI for the above purpose. Sequences of left and right eye winks are used as input to a chair-mounted, battery-powered, miniature computer. The computer, in turn, interprets the wink sequences and issues the corresponding control signals to the wheel motors on the chair. The integration of a dedicated computer into the system greatly extends the command complexity of the two otherwise simple binary input switches (closings of left and right eyelids), thereby enabling a complete set of chair commands to be defined.

Methodology—In the prototype EWCI, intentional eye winks (i.e., controlled closings of either or both eyelids) are registered electronically through pairs of infrared photosensors attached to the temple pieces of common eyeglass frames. One sensor for each

eyelid continually passes the status (UP or DOWN) of the respective lid to a dedicated computer. The computer monitors the length of time that the status of each eyelid remains unchanged. This timed period is then categorized as either (reflex) BLINK, SHORT WINK, LONG WINK, or SUPER LONG WINK. Reflex eye blinks are easily rejected by the computer so that only intentional WINKS are acted upon. The computer also provides audio feedback in the form of a frequency shifting tone to aid in selecting the duration of WINKS. Commands are defined as a combination of the status of the eyelids and the length of time that status was held (e.g., BOTH DOWN—SHORT WINK LEFT DOWN—LONG WINK, etc.). With four possible time lengths and four possible states of the eyelids (two eyes, two positions) there are 16 possible commands that can be issued.

Before attempting to control a powered chair, the operators train with the EWCI at a stationary computer terminal using a graphical simulator. The simulation allows the individuals to gain familiarity with the interface command sequences. When the user is comfortable controlling the "virtual" wheelchair movements in the proscribed area of the

display monitor, mazes of increasing complexity are added to the area. After the user has become proficient at navigating the advanced mazes the client is "graduated" to an actual powered chair.

Results—A subject with C3-4 quadriplegia was selected to test the prototype EWCI in the control of a powered wheelchair. He was able to control a powered wheelchair after approximately 16 hours of combined practice with the virtual and real chair systems. The subject has found the EWCI to be less obtrusive, less fatiguing, and more flexible as a control device than his current chin manipulated joystick.

Future Plans/Implications—At present, motorized wheelchair control is the focus of our project. We have, however, plans to extend the EWCI control

concept, so that a variety of environmental control (door answering, light switching, telephone answering and dialing, TV/VCR operations, etc.) can be manipulated by simple eye wink input. This extended system will use icon-driven menus to select particular actions and will require the addition of a small flat panel display to the wheelchair-mounted computer.

Recent Publications Resulting from This Research

The Eye Wink Control Interface: Using the Computer to Provide the Severely Disabled with Increased Flexibility and Comfort. Shaw RM, et al., in Proceedings of the 3rd Annual IEEE Symposium on Computer-Based Medical Systems, Chapel Hill, NC, 105-111, 1990.

Using the Eye Wink Control Interface to Control a Powered Wheelchair. Crisman EE, et al., in Proceedings of the 13th Annual International Conference of IEEE Engineering in Medicine and Biology Society, Orlando, FL (in press).

[514] Ultrasonic Head-Controlled Wheelchair and Interface

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Sponsor: VA Rehabilitation Research and Development Center (Core Funds); Paralyzed Veterans of America

Purpose—The Ultrasonic Head Control Interface (UHCI) is a device designed to provide severely disabled individuals (quadriplegics) with a means of controlling devices such as electric wheelchairs in a socially acceptable and aesthetically pleasing manner.

Progress/Methodology—In this project, two Polaroid ultrasonic distance ranging sensors are the basis for a new type of human-machine interface. They emit inaudible high frequency sound waves which propagate through the air until reflected by an object. A portion of the signal incident on the object is reflected as an echo and is detected by an electronic system.

The elapsed time from transmission of the signal to the reception of its echo is proportional to the round-trip distance from the sensor to the object. In this rehabilitation application, two separated sensors are directed at the user's head. The two resultant distance ranges, one from each sensor to the head, and the fixed distance between the stationary sensors describe a triangle whose vertices

are the two sensors and the user's current head position. A geometric relationship allows the offset from the base-line and center-line of the two sensors to be calculated. The array of distance ranging sensors can monitor the head position of a severely disabled quadriplegic operator to obtain command and control information for the operation of mobility, communication, and robotic devices.

In operation, the user of an UHCI tilts the head off the vertical axis in the forward/backward or left/right directions. The translation of head position information into electrical signals can mimic the output of a joystick. Both can be used to control devices to which they are attached, such as a wheelchair, a communication aid, a video game, or a robotic arm.

Results—Within Rehabilitation Research and Development (RR&D), UHCIs have been installed on two electric wheelchairs. The first is an E&J model 3P equipped with a reclining Recaro seat and is in use in France by a quadriplegic woman. The second, mounted on an Invacare Rolls IV with a Solo

Products Power Pack, continues to be demonstrated at RR&D and evaluated by Spinal Cord Injury patients at this VA facility.

Both units have been operational since June, 1983. User evaluation has been performed with 10 quadriplegic individuals. After a short demonstration and training session, they were transferred into the chair and most were able to successfully navigate the chair without problem. Users stated that they preferred the ultrasonic head control to the chin-controlled joystick wheelchairs that they had used. The device has proven to be easy to use. Its intuitive operation requires little focused concentration and thus does not result in user fatigue.

Eureka Laboratories of Sacramento was competitively selected to manufacture these devices. The first unit has undergone pilot human subject evaluation at the VA Medical Center in Richmond, VA. The VA Medical Centers in Houston, Tampa, Miami, East Orange, Bronx, Castle Point, Long Beach, Decatur, and San Diego are candidates for the formal clinical evaluation.

Future Plans/Implications—The evaluations are scheduled to be completed by early 1992 with a final report to be published one month later. That document will summarize the results of the study and contain a recommendation regarding the prescription of electric wheelchairs using the UHCI technology for appropriate severely disabled veterans. If an approval is forthcoming, Eureka Laboratories has indicated that they will pursue mass production of the UHCI to satisfy the demand of the VA and other potential purchasers.

The ultrasonic head-controlled technology is also being developed for computer access applications.

Recent Publications Resulting from This Research

A Case Study: The Ultrasonic Head Controlled Wheelchair and Interface. Jaffe, DL, OnCenter—Technology Transfer News 1 (2), 1990.

Ultrasonic Head Controlled Wheelchair/Interface—A Case Study in Development and Technology Transfer. Jaffe DL, Proceedings of the 13th Annual RESNA Conference, Washington, DC, June, 1990.

[515] Smart Wheelchair Survey

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Sponsor: National Department of Supplies and Services, Canada

Purpose—The primary objectives of this project were to: 1) conduct a survey of a number of groups of individuals with a disability and/or professionals working with or for members of these groups within Canada, on the present level of use and reasons for non-use of conventional powered wheelchairs and to identify potential users of enhanced ("smart") powered wheelchairs; 2) conduct a literature search for any previous surveys on similar topics; and, 3) determine what smart features are most needed by persons with particular disabilities.

Methodology—*Literature Review*: As preliminary steps to surveying users and prescribers of powered chairs, the researchers performed a literature review of research in, and surveys about, wheelchairs and smart wheelchairs. Several computer searches of the literature were carried out addressing surveys of

powered mobility needs and problems encountered by persons in four distinct disability groups.

Focus Groups: In order to further determine the issues to be addressed in the survey, a number of "focus groups" of users from the four groups mentioned above, as well as wheelchair providers, were held. Five focus groups were held, each with a different group of users and clinicians. The first four focus groups addressed mobility needs of persons who are 1) physically disabled, 2) developmentally delayed, 3) elderly, and, 4) visually impaired or blind. Participants of a fifth group discussed transportation issues.

Surveys: Two surveys were constructed, partially overlapping in content. The User's Survey, was intended for completion by users or potential users of powered wheelchairs or scooters (62 questions and 226 response options). The Prescribers'

Survey, was to be completed by prescribers of powered mobility devices (42 questions and 218 response options).

Results—The 124 wheelchair drivers and 71 scooter drivers who returned the user surveys are a tremendously diverse and varied group of individuals, as can be seen by the descriptors which follow. They ranged from 8 years to 90 years of age, with a mean age of 49 years and a standard deviation of 18. As might be expected, the average age of scooter users was considerably higher (i.e., 58 years) than the average age of wheelchair drivers (45 years).

In general, smart features received a higher desirability rating from prescribers than from users. Prescribers chose the following features as being desirable: wall-following, door negotiation, failsafe operation (i.e., warns of breakdown but continues to operate), docking at a table (i.e., raising or lowering automatically to avoid bumping into the table's edge, yet allowing the user to access the

table's surface), obstacle detection, warning of the presence of an obstacle, and obstacle avoidance capabilities. In addition, the wheelchair's role as teacher of mobility skills was rated high by prescribers, as was the need for wheelchairs to be equipped with environmental controls, communication devices, and computer access methods. Prescribers also rated highly the ability to operate telephones, automatic tellers, and vending machines from the wheelchair.

Users, on the other hand, appeared much more satisfied with their ability to drive the wheelchair and only subgroups of user respondents rated highly such smart features as wall-following, doorway negotiation, and obstacle avoidance. Wheelchair drivers did not find it desirable for their chairs to play a role in teaching them how to drive better. These responses can be understood if one keeps in mind that the respondents are all current powered wheelchair drivers with an average level of experience of 11 years.

[516] Evaluation of the MANUS Wheelchair-Mounted Manipulator at Work and in the Home and School Environment

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Sponsor: *National Health Research and Development Programme, Department of Health and Welfare, Canada; Rick Hansen Man-in-Motion Legacy Fund*

Purpose—Robotics technology has progressed to the point where prototype manipulator arms can be used to supplement activities of daily living (ADL) for persons who are severely physically disabled. To date, most evaluations of this technology have taken place in research laboratories or treatment centers. This research project is evaluating a state-of-the-art, wheelchair-mounted manipulator arm, developed in The Netherlands, in independent living, vocational, and school environments. The main research question asked is: Does a robotic arm add substantially to the independent performance of ADL, vocational, or educational activities of the user?

Methodology—The design consists of a minimum of 8 and a maximum of 12 single-case studies. Seven adult participants and three children will use the robotic arm for at least 1 month in their daily independent living, working, hospital, or school

environments. Questionnaires, observation scales, and a special video-camera system will be used to collect data. The MANUS manipulator arm will be mounted on each participant's chair at the Hugh MacMillan Rehabilitation Centre (HMRC). Observations and test administrations will be carried out both at the HMRC and in the participant's home, work, or living environment.

Preliminary Results—Results from initial assessment and training sessions indicate that the MANUS arm is a versatile and flexible tool. Its operation is easy to learn, and there is a wide range of activities that the user of the MANUS can perform: picking and placing, drinking and eating, even combing one's hair and lifting heavy objects.

Comments from users and visitors (nationality of person(s) making the comment) include:

- new possibilities for persons with disability (Sweden);
- able to mimic sophisticated movements (South Africa);
- easy to learn, compact, quiet (USA);
- quiet operation, smooth, precise, and accurate; can pick up small objects, easy to learn (Australia);
- speed is OK, wheelchair mounting is a good idea (Canada);
- possibility for persons with severe motor impairments to work three dimensionally (Sweden).

Feats performed with the MANUS arm include:

- lift up Toronto telephone book (2.4 Kg);
- comb hair by drawing hair through comb;
- turn pages of book;

- pour and drink juice, and eat a cookie;
- feed a butter tart to our welder;
- insert 5 1/4-inch diskette into an computer disk drive and close the door.

Future Plans—Two areas cause concerns: the first is related to the control panel, which requires good fine-motor control, and the second is the mounting of the MANUS onto the wheelchair. The control system has caused difficulties for some prospective clients. There is a need to modify the control input so that users can operate the MANUS via the joysticks used to control their wheelchairs. The integration of the MANUS control system with the wheelchair controls will be addressed in a future project.

[517] Improved Gear Box Efficiency

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—The mechanical losses in the gearboxes of an electric wheelchair drive system are a major contributing factor to the inefficiencies encountered in chair operation. The objective of this research is to try to minimize those mechanical losses.

Methodology—The largest amount of loss is due to the high friction forces resulting from the constant sliding action of the worm on the gear. The efficiency in a worm gear is dependent on the lead angle of the worm thread, pressure angle normal to the gear teeth, and the coefficient of friction. For a particular worm gear, the only variable that can be controlled is the coefficient of friction. Different forms of lubrication having varying coefficients of friction were used on the surfaces of the worm and gear. The efficiencies of the gearboxes were then tested by using a dynamometer. The dynamometer displays the input power supplied to the motor and the resulting output power delivered by the gearbox. Using a constant load and various input speeds, resulting efficiencies for both the motor and gear box were recorded. Knowing the efficiency of the motor, efficiency versus wheelchair speed was re-

corded and plotted for the gear box. This was done for each type of lubrication.

Progress—An improvement in efficiency occurred when comparing a typical thick black gear grease to polytetrafluoroethylene, a polymer lubricant. Due to the strong covalent bonds connecting the polymer chain and weak van der Waal forces between the chains, "sliding" is encountered with minimal shear forces. This characteristic results in a very low coefficient of friction. Therefore, the usage of the polymer lubricant would increase the efficiency of the drive train of the electric wheelchair, which in turn increases the travel time of a chair between battery recharges.

Future Plans—Further tests are going to be conducted using molybdenum disulfide, a solid lubricant. It too has similar sliding characteristics between the layers of sulfides, resulting in a low coefficient of friction. Two forms of the molybdenum disulfide are going to be tested. One is a film that will be applied by dipping and then baked on. The other is one in which the lubricant is actually

impregnated into the metallic surface of the worm and gear. An added benefit of the solid film

lubricants is the elimination of the possibility of oil or grease dripping onto floors or carpets.

[518] Design of a Redundant DC-DC Converter for Powered Wheelchairs

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—The goal of this project is the design and implementation of a highly available digital wheelchair controller using redundant hardware. This controller will be able to continue to operate even if portions of it experience failures. A single command sensor (joystick) relays speed and direction information to two identical control systems. Both control systems read the joystick and initiate control signals to motors through a relay. This relay allows one of the systems to drive the wheelchair motors while the other is inhibited. Though only one system is actually controlling the motors at any instant, both are actively involved in fault detection and location. Both systems compare their respective state via a communication scheme implemented in a global memory. If either system detects a miscompare, then both systems initiate a comprehensive series of fault location routines to determine which system is faulty. If one of the systems is able to determine that it is faulty, then the other system assumes control. If neither system is able to locate the fault, then this information is relayed to the user, and both are inhibited. The user may then provide the selection of either system manually in order to override the mutual inhibition. This case is known as "failed safe" in that it failed by not knowing which system to let operate the motors, but failed in such a manner that it is safe. In addition, both systems will periodically exchange the responsibility of the overall wheelchair control in order to allow active testing of their respective functions.

Methodology—The joystick uses miniature optical encoders and counter integrated circuits. The optical encoders produce pulses which are transmitted to the counter chips as the joystick is moved along either of two axis: forward-reverse and left-right.

These counters have an eight-bit interface to the microcontroller so that it can be read at any instant. This arrangement is duplicated for the other system.

The controller uses a single chip microcontroller, local memory, and two pulse width modulated (PWM) motor controller chips. The microcontroller periodically reads the joystick values and updates the command register of the PWM chips. The local memory is used to store the control and diagnostics routines. The PWM chips generate signals to the DC-DC converter. They also receive feedback from the motors and update the PWM signals based on their own integral/velocity control algorithms.

The DC-DC converter uses level shift and bootstrap interface chips and power MOSFETs arranged in an H-bridge configuration. Bootstrapping must be performed, since all nFETs are used in the H-bridge. The motor arrangement uses a relay, a permanent magnetic DC motor, and a shaft optical encoder for velocity feedback.

Results—A preliminary version of the joystick has been built and tested. The final version has been built and will be tested in conjunction with the microcontroller. The controller design has been completed and is currently being built. The H-bridge has been completed and tested under "no load" (i.e., not connected to motors) conditions.

A preliminary version of the control and diagnostics software has been written. The control software includes routines to initialize the microcontroller operations and read from the joystick and convert this position to a command velocity to be written to the PWM chip. The diagnostics software includes routines to check the microcontroller and test the H-bridge configuration when that system is not in use.

Future Plans—The current implementation can only accommodate failures in duplicated parts by detection and location of a faulty part. However, methods to predict when failures may occur in the nonredundant parts, such as the motors and the frame, are currently being addressed.

[519] Design of a Software Package for Fault Tolerance Analysis of Electric Wheelchair Systems

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—It is an unfortunate fact that most powered wheelchair designers do not possess the tools nor the knowledge to perform system dependability analysis using mathematical analysis techniques such as combinatorial and Markov chain modeling. Research at the University of Virginia has produced a software tool that would address this shortcoming. Titled WCpc, the software is a dependability analysis tool whose goal is to automate the process of modeling dependable powered wheelchair designs. Much effort in the research has been placed on providing an adaptable design environment for the engineer so that WCpc can be useful to the designer whose expertise in dependability analysis ranges from the totally naive to the sublime. The organization of WCpc can be described as a hierarchically arranged database of components that are modeled using a dependability modeling engine. Wrapped around the database and engine is a front end which takes advantage of the graphical capabilities of an IBM-compatible personal computer (PC). This front end can present to the user a character-based visual representation of the system as well as color graphics plots of the dependability measures of a system.

WCpc was designed with the following goals in mind:

- **Hierarchical design**—During the modeling of a system, the user is made to structurally decompose the system into a hierarchy of substages. This approach facilitates the use of fault-tree

Recent Publications Resulting from This Research

Redundant DC-DC Converter for Powered Wheelchairs. Prasad RK, Aylor JH, Johnson BW, in Proceedings of the 13th Annual Conference on Rehabilitation Technology, Washington, DC, 405-406, 1990.

methods to calculate the global dependability measures for the system.

- **Support for comparative analysis of architectures**—WCpc provides the designer with multiple case studies of any substages that are defined in the model constructed. As the dependability measures for each case study are generated, they can be presented on the CRT display to assist the user in making design trade-off decisions.
- **Support for both Markov chain analysis and combinatorial modeling of substages**—A key feature to WCpc is the ability to automatically generate state transition matrices for Markov chains from a high-level syntax.
- **Incorporation of non-constant failure rates in dependability analysis**—In order to more accurately model electromechanical and mechanical components, WCpc features the ability to use non-constant Weibull-distributed failure rates for component descriptions.

Progress—The software system is currently being evaluated at the University of Virginia. Both existing wheelchair designs and a new design based on a fault-tolerant, microcontroller-based system are being evaluated using the software tool.

Recent Publications Resulting from This Research

A Software Package for the Fault Tolerance Analysis of Electric Wheelchair Systems. Jurgens CY, et al., in Proceedings of the 13th Annual Conference on Rehabilitation Technology, Washington, DC, 45-46, 1990.

[520] Serial Wheelchair Control Interface Standard

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—As electronic communication aids and environmental control devices become more advanced, their ability to perform more sophisticated functions expands. As a result of this increased capability, there is a growing interest in interfacing suitable assistive devices (such as communication aids) to wheelchairs. In this model, the aid assumes the control functions typically performed by the joystick or other standard control built into the wheelchair. However, devices such as communication aids can only be used as controls if they can be effectively interfaced to the wheelchair. At the present time, special aids must be individually customized for each model of wheelchair with which they are to be used. No common interface exists among powered wheelchair controllers, but several manufacturers are interested in developing them.

Progress—To assist in the development and application of new control devices, Trace Center engineers have begun developing a protocol for a standardized connection. As long as both the control and the wheelchair conform to the specifications of the standard, any manufacturer's control device can be used with any manufacturer's wheelchair.

Methodology—The standard uses a serial data transmission format for the interface and defines a set of specific codes to be sent to achieve particular wheelchair control actions. The standard also sets down electrical specifications (voltage, resistance, etc.) and connector types and connector pin assign-

ments. The standard is circulated in draft form to interested parties in the field, and their comments integrated into future revisions.

Results—The standard was discussed in meetings of wheelchair manufacturers, communication aid manufacturers, and researchers at the annual RESNA conferences in 1988, 1989, and 1990. Version 3.2 of the draft proposal has been completed. A RESNA subcommittee on wheelchair standards has been created to review and further develop the standard. Since RESNA is the representative on wheelchair issues to ANSI, the standard is also under consideration for adoption by ANSI. RESNA, through ANSI, submitted an application to the International Standards Organization (ISO) to establish a working group on the standard within ISO. In November, 1990 the working group was established.

Future Plans—The Trace Center and the RESNA subcommittee will continue to work on the standard and to support ISO in its development and adoption. This process is expected to take several years. Copies of the standard are available to any interested parties through the Trace Center Reprint Service.

Recent Publications Resulting from This Research

Serial Wheelchair Control Interface Standard. Schauer JM, Vanderheiden GC, Kelso DP. Madison, WI: University of Wisconsin, Trace Research and Development Center, 1990.

[521] The MIT Damped Joystick: A Control Interface for Tremor-Disabled People

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Sponsor: Burke Rehabilitation Center, White Plains, NY; National Institute on Disability and Rehabilitation Research, via Harvard-MIT Rehabilitation Engineering Center

Purpose—The intention tremor or cerebellar ataxia often seen in people with multiple sclerosis and head injury precludes independent motor activities of many kinds. In particular, use of joystick-controlled powered wheelchairs is commonly ruled out because of unacceptable inaccuracy of direction and speed control caused by the tremor. While several available chairs include electronic filtering as a feature, this has disadvantages including failure to deal with the visible shaking of the user's hand. To deal with this problem, the tremor group in the Newman Lab has developed the MIT Joystick which incorporates viscous damping. It does so by means of a simple chamber of 2,500,000 centistoke silicone grease through which an extension on the joystick shaft moves as the joystick handle is moved. One hypothesis is that, unlike downstream filtering, this energy-dissipating load will have a compensator-like effect on the neural control loops generating tremor so that the oscillatory muscle torques driving the tremor will be reduced rather than opposed.

Progress—Objective tests of the MIT Joystick with a small number of tremor-disabled subjects showed statistically and clinically significant reduction in

tremor and improvement in signal-to-noise ratio. Subject reactions have been highly favorable. Since the last progress report, a third generation of the MIT Joystick has been designed and built. It features improved manufacturability, a built-in fast-stop switch (so that damping need not limit the speed of an emergency stop), interchangeable grips, 20% reduction in size, and hidden calibrated external adjustment of damping.

Future Plans—A protocol has been developed for simple clinical evaluation of wheelchair driving skill using the joystick. It involves measurement of a "Fitts constant" relating the required accuracy of steering task to the speed with which it performed. It is hypothesized that this constant will be improved by the optimal amount of damping, i.e., that greater speed will be possible for a given accuracy. Technology transfer efforts continue.

Recent Publications Resulting from This Research

A Second-Generation Joystick for People Disabled by Tremor. Hendricks JL, et al., 14th Annual RESNA Conference, Kansas City, MO, 1991.

[522] Gamma Controlling Devices for Accumulator-Powered Wheelchairs

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Sponsor: None listed

Purpose—The goals of this work are to: 1) create an electronic device for the control of accumulator wheelchairs to be industrially manufactured in Bulgaria; 2) create and experimentally verify algorithms of control for a wheelchair with two driving wheels and two self-directing wheels; and, 3) outline mea-

asures to increase the maneuverability and dynamic stability of the wheelchair.

Results—Several algorithms were developed to process the joystick signals. Three industrial prototypes were designed following the algorithms. One of the

controlling devices was exhibited at the World Salon of Inventors at "Brussels Eureka 1990." A mathematical criterion for motion stability was developed after an analytical study of the mechanical stability of a wheelchair with two driving and two self-directing wheels. A hardware device, realizing the criterion, was designed as well.

The device analyzes the operator's command before fulfilling it. The command is automatically modified if it is established that the direct fulfillment would cause instability or chair turnover. The command modification does not change the desired trajectory, but corrects the velocity and acceleration.

Future Plans—A prototype of a medical manipulator with four degrees of freedom plus gripper has been designed. The manipulator is controlled by the motion of the operator's head and eyes.

The next step will be to design a unified general controller for a medical manipulator/wheelchair complex using minimum supervision of the operator's participation in the complex control.

Recent Publications Resulting from This Research

Conditions for a Wheelchair's Stability Keeping. Stefanov D, Theoretical and Applied Mechanics, Vol 3, Sofia, Bulgaria, 1991.

C. Seating Systems

[523] Computer-Aided Design Package for Wheelchair Seating Systems

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Sponsor: The Cleveland Clinic Foundation

Purpose—Earlier research has described the development of a contour measurement system which is used to quantify seated body shapes and fabricated custom support systems. Present efforts have focused on the development of the user interface to the system. A unique computer-aided design package has been developed to meet the demands of custom body support design.

Methodology—The software is represented as a mouse-driven interactive graphics interface. Shape information is provided to the user in a wire frame format. Two viewports depict transverse and longitudinal cross-sections of the contour. A menu provides access to different functions, which will be described below. Contours can be modified by selecting points or areas with the mouse. As a point is selected on the wire frame, the corresponding cross-sections which pass through that point are presented in the respective viewports. Data points may also be selected within each viewport with the corresponding changes being reflected in the wire frame and remaining viewport. Coordinate values

for the selected data points are provided in each viewport.

As the program is initialized, the *Main Menu* banner appears. Selecting *Main Menu* causes the full menu to appear. From the main menu five basic options are available: *File*, *Frame*, *Cursor*, *Sample*, and *Modify*.

Selecting *File* causes the *File Menu* to appear. Within the *File Menu* the user may exercise four file operations. By selecting *Dir* the user may scroll through the data files in the current directory and may load a file by selecting it with the mouse. The *Load* and *Save* functions require keyboard entries. Patient data can be entered and stored by selecting *Edit File*, which invokes a full screen editor.

The *Frame Menu* provides three options: *Translate*, *Rotate*, and *Grid Size*. *Translate* allows the wire frame to be moved up, down, left, or right on the screen. The *Rotate* function allows the wire frame to be rotated clockwise or counterclockwise as well as toward either vertical or horizontal. Finally, the *Grid Size* menu allows the user to select the size of the grid to be displayed based on the number of slices in the data set.

The *Cursor Menu* allows the user to select the mouse functions. *X Line* affects all points on a single slice running from left to right through the selected point. By moving the single point either up or down the whole slice is affected, with all points following the height of the selected point. *Y Line* works in a similar fashion but affects all points on a single slice running from front to back. *Area* allows the user to mark a rectangular area by selecting two points on the grid. Once the area has been selected it is highlighted. By selecting any point within the highlighted area, the user can move the entire area to the desired level. *Restore* allows the user to select an area and then restore all data points within that area to their original displacements.

The *Sample Menu* allows the user to sample contour data. Using the contour measuring device described in earlier research, data is acquired one slice at a time. Slices may be resampled using the *Repeat* function.

Finally, by selecting *Modify*, the *Main Menu* is replaced with the *Main Menu* banner, and the screen becomes live for modifications.

Results—This work has resulted in a useful means of quantifying and representing seated body shapes. The mouse-driven menus facilitate use of the CAD package, requiring little user training beyond a demonstration of each function. The CAD package facilitates visualization of contour data. Data may be easily modified, and changes may be archived along with other patient information.

Recent Publications Resulting from This Research

Computerized Shape Reproduction for Custom Contoured Wheelchair Systems. Neth DC, Reger SI, in Proceedings of the 7th International Seating Symposium, 1991.

[524] Development and Clinical Evaluation of an Adjustable Modular Postural Seating System for Persons with Mild to Severe Physical Involvement

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Sponsor: National Health Research and Development Programme, Department of Health and Welfare, Canada

Purpose—The objective of this project is to develop and evaluate a cost-effective seating system that will interface with a wide range of available seating components, require few parts, and be easy to dispense with readily available hand tools. The specific goals are to: 1) develop and evaluate a system of adaptable, premolded plastic shells; and, 2) prepare and evaluate a training package to assist seating clinics in dispensing the system.

Methodology—The system consists of a back pan, seat pan, upholstered foam seat cushion and back covering, interfacing hardware, headrest, footrest, and contoured lateral supports.

The back shell is a simple, one-piece, three-sided thermoformed pan made of ABS that has been produced in three widths. It is oversized in length to enable customization of the pan by trimming. The back is configured to locate between the uprights of

the wheeled base; however, with the addition of straps the pan can be secured in an upright position in front of the push-handles. Securement and inclination of the back are provided by two sets of interfacing hardware. Both sets are semipermanently attached to the wheelchair push-handles, with the lower set located such that there is no interference with the upright bushings as the chair is folded. Adjustment to the interfacing hardware enables various widths of wheelchair bases to be accommodated.

Torque knobs are provided with the upper clamps to both release and secure the back module. The lower set of clamps receives posts mounted on the edges of the molded lips of the back. By raising the back about 1 inch, the back shell can be removed. The seat shell is also molded ABS with a lip on one side to fit onto the rails of the wheeled base. It is provided with an inclined 2 inch drop base

to avoid interference with the wheelchair cross bars, and is located by two posts that use the standard upholstery holes in the seat rails. With its overlapping design, it can be readily adapted to most wheelchairs from a seat width of 10–20 inches. The seat shell is configured to accept either commercially available or poly-foam cushions.

The seat cushion consists of a vinyl (Melohyde) top covering and stretchable lycra bottom, pre-stitched with one-half-inch low-density foam. An opening in the lycra is provided to allow the desired thickness and shape of foam to be inserted for customization of the cushion interface.

The back upholstery consists of oversized vinyl covering, provided with 1-inch-thick foam, which can be trimmed to size at fitting. Both the back and seat cushions are secured to the pans by hook-and-loop fasteners.

Progress—To date, four of seven clients have been fitted with the prototype system. Evaluation of the systems after 3 months of use will assist in identifying *in situ* performance of the system. Also, two other seating clinics in the Toronto area will be fitting systems to provide objective feedback regarding the ease with which the systems are fit.

Preliminary Results—Preliminary results of the initial fittings found that: 1) the use of the modular adjustable seating system appears to reduce the amount of time required to dispense a seating system for a client with mild to moderate physical involvement; 2) the present system appears to be suitable for a number of commercially available cushions and wheeled bases; and, 3) the vinyl cushion readily packages various shapes and densities of foam to customize the “comfort and support” interfaces for the client presenting with mild to moderate physical involvement.

Caregivers have reported on ergonomic issues relating to the system. Generally, they have found the systems to be relatively easy to insert and remove. They have found the components to be durable and functional for their children. They also reported the desire to have a system that could be readily dispensed in one appointment.

While only preliminary qualitative assessments have been obtained for the prototype system, other issues, such as moderate inventory requirements, obstructed adjustments, and weight, must be addressed before a commercial system is realized.

[525] Research and Development to Improve Seating Design

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—Development of decubitus ulcers is a significant problem for individuals with limited mobility due to the large amount of time spent motionless in a supporting structure. The purpose of this research is to develop a desktop computational tool to be used in the design of wheelchair seating systems and other pressure relief positioning devices. The finite element computer program under development can be used to determine the pressure distribution within the tissues of the buttocks. The ultimate goal of this work is to provide affordable, pressure relief devices for the disabled.

Methodology—This phase of the research was divided into two parts: 1) quantification of the

necessary anatomical data, and 2) development of a finite element computer program for the analysis.

In order to correlate pressure with tissue distortion, a contour seating gauge was used to experimentally determine the relationship between force and deflection of *in vivo* fat and muscle. The geometrical dimensions of the tissues of the pelvic region of a nondisabled male subject and a nondisabled female subject were measured using magnetic resonance imaging (MRI).

Special routines were written for the computer program to deal with the unique characteristics that arise when dealing with biological tissues. Specifically, algorithms were created to deal with the nonlinearity of the material properties and the large

amount of data needed to describe the complex anatomical structures.

Preliminary Results/Future Plans—The experimental results of the tissue property investigation show that the relationship between force and tissue distortion has both linear and nonlinear regions within the force-displacement curve. The preliminary computational work focused on the linear analysis. Internal

stresses were calculated throughout the right buttock for each subject in both seated and supine positions on foam custom contour cushions. Preliminary results show areas of high stress around the ischial tuberosity.

Work is continuing on combining both linear and nonlinear analyses. Results will be verified with experimental data gathered with the MRI.

[526] Development of Improved Seating Assessment: Prescription and Review Procedures

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Sponsor: *Scottish Home and Health Department*

Purpose—Existing procedures for assessing patients for seating are largely subjective. Measurements of the effectiveness of different sitting postures in meeting the individual's seating requirements are lacking. Prescription of seating and review are in turn limited by these procedures.

The basic aims of this project are therefore to:
1) develop methods and equipment for quantifying the effects of different sitting postures; 2) develop improved assessment and review procedures incorporating these methods; and, 3) undertake a preliminary monitoring program, using the improved assessment and review procedures, in order to determine the practicality and potential benefits of these procedures.

Progress/Methodology—*Clinical Procedures.* Assessment procedures and documentation used at the Dundee Limb Fitting Centre for defining the individual's seating requirements have been revised. Content and presentation of information has been improved. The new procedures have been adopted by the clinic team, and are under evaluation.

The following instrumentation for the measurement of specific variables associated with seating is being developed and integrated into a practical system for use in the clinic.

Measurement of Muscle Activity. Measurements of muscle tone and spasticity using electromyography (EMG) are being investigated. The potential clinical value of such measurements,

in relation to posture and body orientation will also be evaluated. Apparatus for monitoring muscle activity, via surface electrodes, has been developed. Preliminary results show that it is capable of providing comparative measures of muscle activity.

Interface Pressure Measurement. A mapping of the body/support interface pressure was required as part of the clinical measurement system. A simple dynamic pressure measurement monitor was selected comprised of an array of oil-filled capsules connected via tubing to piezo-resistive pressure transducers. The accuracy and frequency response of this monitor are being examined.

Measurement of Joint Angles. It is assumed that a simplified picture of sitting posture can be characterized by measurements of joint angles at the hip, knee, and ankle. Measurement of upper body joint angles may be added at a later stage. Twin-axes flexible goniometers are being used to make the measurements.

Data Acquisition. The information from the above measurement devices is recorded in real time by a personal computer via data acquisition hardware and software. Simultaneous measurements will allow an investigation of the influences of changes in posture, and hence joint angles, on EMG and interface pressure measurements.

Measurement of Spinal Shape. An estimation of spinal deformity represents another element of the system. An Integrated Shape Investigation System (ISIS) is being used.

Preliminary studies have been based on an analysis of the surface topography of positive casts taken from molded seats. Such casts are believed to reflect the back shape of the individual in a supported posture. This technique will allow a long-term monitoring of spinal shape as achieved in consecutive molded seats.

Future Plans—If appropriate, further funding is to be requested to continue development of patient assessment procedures, and to conduct long-term monitoring of patients requiring seating.

[527] Application of the Finite Element Method for Design of Seats and Seating Systems

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Sponsor: *Moscow Aviation R&D Institute*

Purpose—The main purpose of this project was to analyze structures of different types of passenger seats (general aviation, automotive, and wheelchairs) under different loads, and to demonstrate to manufacturers and designers that high-cost static and dynamic tests are not necessary in the preliminary design stage.

Progress/Methodology—The work consisted of developing finite element models for passenger seats for general aviation, vans, and buses, as well as for wheelchairs. Detailed analysis was performed for two particular models: aviation passenger seats and manually-powered wheelchairs.

The DIANA-software and EC-1033 Mainframe computer were used to perform computations. The 3-D finite element models of the seats consisted of 2,400 elements, and the frame was simulated by beam and plate elements with known parameters. Passenger weight was simulated by 80 kg weights; the frame was assumed to be loaded according to static measurements and our own preliminary computations of specific loads from seat belts.

Results/Future Plans—Static and dynamic (free vibration) analyses of these models were performed. In the static analyses, FAA and CAA (Great Britain)

rules were used for determination of the loads, and as a criteria of failure. Critical zones were found and recommendations were made about design changes.

The first stage of the dynamic analysis was performed for these models. The frequencies of the system of the "human body seat" were determined. For situations when high dynamic loads are present in the system, intensive vibro-accelerations and vibro-displacement of some parts of the particular human body (eyes, heart, etc.) may appear due to the resonance effect. For nonimpaired persons, such short-term vibration generally can be absorbed by his/her own body, but this is absolutely impossible for a person with some form of disability.

The two next stages planned for this work are: a full vibration analysis of seating structures (including forced vibration) to be performed separately for able-bodied passengers, and also persons with disabilities, in order to eliminate or decrease the above-mentioned problems; and, analytical crash-test simulation must be performed to determine the level of loads and stresses during real accidents and crash simulations similar to the University of Michigan slide tests. Therefore, the time required for new design approval and the cost of tests can be significantly decreased.

XVII. Wound and Fracture Healing

A. Pressure Sores

[528] Enhancement of Wound Healing Using Synthetic Skin, Electric Stimulation and Hyperbaric Oxygen Therapy

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Sponsor: VA Rehabilitation Research and Development Service (Project #A447-RA)

Purpose—Our group has evaluated the promotion of dermal and epidermal healing of bed sores treated with type I collagen flakes as compared to a type I collagen aerosol. Results of previous studies indicate that type I collagen in the form of flakes promoted healing of stage II and III bed sores in 85% of patients as compared to controls. The purpose of our current study was to evaluate the use of a new aerosol form of collagen type I for treatment of bed sores.

Methodology—Five patients with chronic bed sores were treated with collagen flakes, while an additional five patients were treated with an aerosol form of collagen produced by Micro-Collagen Pharmaceuticals (Bangor, PA). All patients signed informed consent forms and were treated daily for 3 weeks prior to treatment with collagen using a standard protocol consisting of a daily saline wash, followed by application of a wet-to-dry gauze dressing. In cases where necrotic tissue was present, wounds were debrided prior to collagen treatment. The surface area was measured weekly by placing a clear plastic sheet over the wound and tracing the wound perimeter. After 3 weeks of treatment, the wounds were then treated once a day using collagen flakes or a collagen aerosol spray after the saline washing step. Treatment was followed by application of saline wetted gauze and the dressing was secured to the surrounding normal skin using adhesive tape. Wounds were treated with collagen for a total of 12 weeks.

Results/Implications—From a procedural point of view, use of the aerosol form of collagen has distinct advantages over the use of flakes. Unlike collagen powders, which are difficult to handle because of their high surface charge, flakes are not electrostatically charged and can easily be packed into a wound; however, they can cause some discomfort to the patient. The nurse doing the therapy must be careful not to contaminate the flakes by inadvertently touching them against the skin adjacent to the wound of the patient.

In comparison to flakes, the collagen spray can be quickly administered to the wound without fear of contamination and its alcohol base may have a bactericidal effect.

Results obtained in this study suggest that wounds treated with a collagen aerosol showed healing that was similar to wounds treated with control collagen flakes. A 50% wound area reduction was observed in patients treated with collagen flakes or the collagen aerosol over a time course of about 6 weeks.

Although collagen flakes have been shown to improve healing of bed sores, they are difficult to pack under skin flaps and often result in discomfort to the patient. Results of studies conducted using a collagen aerosol spray indicate that it offers advantages such as ease of application and reduced discomfort with respect to use of collagen flakes. In addition, reduction of the wound area observed with the spray is similar to that observed with the flake form of the material.

Our results indicate that initiation of healing of bed sores is promoted by type I collagen. Use of an aerosol form of collagen offers distinct advantages

over flakes or other physical forms, and results in comparable wound area reduction.

[529] Phosphorus NMR Spectroscopy of Normal and Diabetic/Ischemic Skin: A Pilot Study

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Sponsor: VA Rehabilitation Research and Development Service (Project #A90-129AP)

Purpose—In our pilot project, we are testing our hypothesis that there are measurable differences in the nuclear magnetic resonance (NMR) spectrum of intracellular adenocine-triphosphate (ATP), phosphocreatine (PCr), and inorganic phosphate (Pi) between diabetic/ischemic and nondiabetic/nonischemic skin. The skin is tested under nondiabetic/nonischemic and challenged conditions. This technology has profound clinical and research applications in that, by measuring the relative concentrations of intracellular phosphorus compounds, one essentially measures the intracellular energy in skin. We believe that ultimately this technology will accurately enable us to predict wound-healing potential, and to measure the positive or negative effects of various wound-healing treatments and adjuncts on the wound-healing potential of skin.

Progress—We have measured these signals in two human subjects using a General Electric, CSI-2, 2 Tesla NMR spectrometer located at the University of Washington. The University recently changed the magnet configuration and bore of the research spectrometer to improve the quality of spectroscopy. The downtime delayed our testing of nondiabetic/nonischemic subjects and required redesign of our coil and foot platform. Systematic study of nondiabetic/nonischemic skin and the phosphorus spectroscopic patterns of skin in response to stresses of temperature, elevation, pressure, and ischemia has begun. The patterns of diabetic and ischemic skin to predict wound-healing for amputations or reconstructive surgery will then be measured.

Methodology—Nondiabetic/nonischemic skin will be studied on five human volunteers. Human sub-

jects study approval has been granted through the University of Washington human subjects committee. Skin will be studied on the dorsum of the foot, skin which is often associated with wound-healing problems and has little subcutaneous tissue and underlying skeletal muscle. Nondiabetic/nonischemic skin will be studied at body temperature and after warm (45 degrees C) and cool (30 degrees C) stress. Skin will also be studied after elevation and dependency, with the application of local pressure, and after the application of topical agents. Equipment reproducibility and accuracy will be monitored using standard solutions of bioactive phosphorus compounds. Ten diabetic patients with planned forefoot reconstruction or amputations will be studied to get the preliminary assessment of predicting wound-healing potential, and differences from nondiabetic/nonischemic skin by measuring the ratios of intracellular ATP, PCr, and Pi.

Results—Phosphorus spectra from nondiabetic/nonischemic unchallenged human skin were obtained. No results from the challenged situations, or from diabetic/ischemic skin are yet available. The spectra obtained from nondiabetic/nonischemic skin are of good quality, and the signal to noise ratio is very comparable to data obtained from previous animal studies. No other human data is available for comparison.

Future Plans/Implications—Because of downtime, the estimated date for finishing this pilot project will be September 1992. The healing of diabetic foot ulcers, reconstructive surgical wounds, and amputations is especially critical to the mission of the Department of Veterans Affairs because of the large population of diabetic and peripheral vascular dis-

ease patients for which we provide care. We do not yet have the technology to accurately predict which ulcers or surgical wounds will heal, and we cannot measure the cellular effects of our various treatments used to enhance wound-healing. The measurement of intracellular ATP, PCr, and Pi could serve as a measure of wound-healing potential to better predict the healing of diabetic ulcers, reconstructive

surgical wounds and amputations. Phosphorus NMR spectroscopy could be a tremendous research tool to measure the efficacy of the various new adjuncts to wound-healing such as platelet derived growth factor, prostaglandin inhibitors, and serotonin derivatives all of which are currently being developed.

[530] Therapeutic Intervention for Healing Pressure Sores with Electrical Stimulation in Persons with Spinal Discontinuities

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Sponsor: Ministry of Science and Technology, Slovenia; National Institute on Disability and Rehabilitation Research, U.S. Department of Education; Commission of the European Communities, Directorate General for Science, Research and Development, International Scientific Cooperation

Purpose—In spite of extensive work in the field of wound healing enhancement by means of electric stimulation, which was conducted during the last three decades, we are still searching for optimal stimulation modality. The aims of this multicenter study are to provide scientific evidence about the effects of electrotherapy on wound healing and to gain insight into the underlying mechanisms. Special attention is being paid to design of the study with regard to the size of the studied sample of patients, control group, and evaluation procedures.

Methodology—Comparative study of the effects of locally applied tetanizing currents (trains of biphasic, charge-balanced current stimuli with the frequency of 40 Hz and amplitude below the visible muscle contraction) versus weak constant direct current (amplitude of 0.6 mA) is being conducted. Pressure sores and wounds due to peripheral vascular insufficiency in patients with spinal cord injury are being stimulated daily for 2 hours using surface electrodes, placed on the healthy skin in the wound surroundings. Weekly measurements of wound size represent the basis for calculation of relative healing rates and further statistical analysis. In addition to the clinical study, several basic studies are underway (measurement of endogenous potentials, bacteriological analyses, *in vitro* study of the effects of electric stimulation on fibroblasts proliferation).

Results—Up to the present, 77 wounds were stimulated with tetanizing current, 15 wounds were stimulated with DC current, and 32 wounds received conventional treatment only. The Student's *t*-test between the groups reveals highly significant differences in the rate of healing in AC treated wounds with regard to controls ($p < 0.005$). The effect of DC treatment, although existing, is not significantly different from that obtained in the control group.

Recent Publications Resulting from This Research

- Effects of Electrical Stimulation on Wound Healing. Vodovnik L, et al., in Proceedings of the 1st European Conference on Biomedical Engineering, Nice, France, 133-134, 1991.
- Endogenous Potentials of Human Skin Injuries. Jerabcinović A, et al., in Proceedings of the 14th Annual RESNA Conference, Kansas City, MO, 1991.
- Promoted Healing of Chronic Wounds due to Electrical Stimulation. Karba R, et al., *Wounds* 3(1):16-23, 1991.
- Response of Fibroblasts to Low Intensity Direct and Biphasic Currents. Kolenc-Krajnik A, et al., *Periodicum Biologorum* 93(2):283-284, 1991.
- Tetanic Versus Direct Currents in Treatment of Pressure Sores. Turk R, et al., in Proceedings of the 4th European Congress on Research in Rehabilitation, Ljubljana, Slovenia, 60, 1991.
- Use of Electrical Stimulation in Wound Healing. Prebšern-Strukelj M, et al., in Proceedings of the 4th European Congress on Research in Rehabilitation, Ljubljana, Slovenia, 60, 1991.

[531] Effect of Electric Currents on Wound-Infecting Microbes

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Sponsor: Ministry of Science and Technology, Slovenia; National Institute on Disability and Rehabilitation Research, U.S. Department of Education; Commission of the European Communities, Directorate General for Science, Research and Development, International Scientific Cooperation

Purpose—In clinical studies using electric stimulation for management of wounds, in addition to enhanced healing, antimicrobial effect of electric current was often also observed. How does electric current being used for stimulation of wound healing actually affect pathogenic wound-infecting microbes? In order to find an answer to this question, an *in vitro* study was performed.

Methodology—An attempt has been made to approach the conditions in the wounds as much as possible in order to enable relation of the results of this *in vitro* study to *in vivo* conditions (wounds). Changes in microbe growth and bacterial susceptibility to antibiotics due to electric currents were studied. Microbes were exposed to low-intensity constant direct current of 0.2 to 1 mA and trains of biphasic, charge-balanced pulses of 40 Hz (subthreshold tetanizing currents in wound stimulation) for 2 to 18 hours. The electric currents were conducted using two experimental systems: Pt-Ir electrodes directly immersed into the culture medium and agar bridges that prevented the electrochemical reactions at the metal electrodes to influence microbial growth. In the trials, strains of microbes that are commonly found as infectants of open skin wounds were used.

Results—Alternating current had no effect on microbes irrespective of the system used. Weak constant current at the metal electrodes induced reactions in the agar that were lethal for all tested

microbes. The inhibitory action (area of sterile zones around the electrodes) was proportional to the magnitude and application time of the electric current. Using the experimental system with agar bridges, however, growth inhibition was found only in *Candida albicans* yeast, whereas bacterial growth remained unaffected. Thus it was interesting to note increased susceptibility of the tested bacteria to antibiotics due to application of the constant direct current that shows on their synergistic action.

Implications—The experimental system with electrodes directly immersed into the culture medium resembles the *in vivo* conditions where one of the stimulation electrodes overlays the wound. According to our results, combination of such electrode positioning and weak constant direct current might have antimicrobial effect in the wound. The experimental system with agar bridges, on the other hand, mimics the *in vivo* conditions where both stimulation electrodes are placed on healthy skin in the wound surroundings. Of the tested microbes, only the growth of *Candida albicans* yeast was inhibited. The observed effect of increased bacterial susceptibility to antibiotics needs further research.

Recent Publications Resulting from This Research

Electric Current as a Mediator of Bacterial Growth and Susceptibility to Antibiotics. Karba R, Vodovnik L, Gubina M, in Proceedings of ETAN (in Slovene, English abstract), Belgrade, 1991.

Growth Inhibition in *Candida albicans* due to Low Intensity Constant Direct Current. Karba R, Gubina M, Vodovnik L, J Bioelectr, in press.

[532] Treatment of Pressure Ulcers

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Sponsor: National Institute on Disability and Rehabilitation Research

Purpose—Development of improved clinical protocols may help reduce the staggering morbidity statistics resulting from pressure ulcers in people with spinal cord injury (SCI). In order to develop optimal active treatment protocols for pressure ulcers, basic wound-healing research is essential. The objectives of this study are to determine, in cell culture, the optimal concentration of oxygen and growth factors for fibroblast activation and macrophage deactivation; to test these optimal levels along with a pulsatile electromagnetic field (PEMF) for healing of full-thickness skin defects; and to evaluate the efficacy of these treatments on pressure ulcers in patients with SCI.

Methodology—The optimal concentration of oxygen for fibroblast activation and macrophage deactivation was determined by growing cells in a controlled environment. The optimal concentration of heparin binding growth factor (HBGF-1) and platelet-derived growth factor (PDGF) was also determined by *in vitro* tests of cellular metabolism and cell growth. The growth factors exhibiting the greatest potential were incorporated into polylactic acid (PLA) and collagen matrices and retested in cell culture.

The optimal growth factor systems and optimal oxygen concentrations, as determined *in vitro*, were tested for full-thickness defect healing in rabbits. For the oxygen treatments, 70% oxygen for 3 hours each day, was used to approximate the optimal *in vitro* condition. In addition, two dressings with different oxygen permeability were used in order to examine the effect of altering the oxygen gradient. Further, a 2–2.8 m Tesla magnetic field (75 Hz) was also tested for full-thickness defect healing in rabbits.

Preliminary Results—During the first 2 1/2 years of the grant period, the following progress has been made: 1. Optimal *in vitro* cellular response was

obtained with 25% oxygen treatment (195 mmHg) and 5 units/ml of growth factor. 2. Both HBGF-1 incorporated into collagen films and PDGF incorporated into collagen sponges significantly increased fibroblast proliferation over the controls. 3. Although no consistent pattern was seen with the growth factors incorporated into PLA films, no signs of toxicity were present. 4. The 70% oxygen treatment significantly sped up the healing process in the rabbit. The more oxygen impermeable dressing led to a slightly better histological response than the more permeable dressing. 5. The PEMF also significantly sped up the healing process in the rabbit model. 6. Initial *in vivo* testing of collagen and PLA/PGA materials with growth factors also showed increases in the healing rate in the rabbit model.

Future Plans—*In vivo* testing will continue, and clinical trials will be initiated during the next 2 years of this 5-year project.

Recent Publications Resulting from This Research

- The Design and Evaluation of PDGF Releasable Implants for Optimal Fibroblast Activation. Estridge T, Feldman D, presented at the 17th Annual Meeting of the Society for Biomaterials, Scottsdale, AZ, Trans Soc Biomat 13:76, 1991.
- Effect of Oxygen and Oxygen Permeability on Wound Healing Using Polyurethane and Polyacrylonitrile Membranes. Pandt A, Feldman D, Estridge T, Trans Soc Biomat 13:138, 1991.
- Effect of Oxygen Permeable and Impermeable Dressings with Varying Oxygen Gradients on Wound Healing. Pandt A, Feldman D, poster presentation at 1991 Annual Meeting of the Federation of American Societies for Experimental Biology, Atlanta, GA.
- The Use of Low Frequency Pulsating Electromagnetic Fields in the Treatment of Full-Thickness Skin Defects in the Rabbit Model. Andino R, Feldman D, poster presentation at 1991 Annual Meeting of the Federation of American Societies for Experimental Biology, Atlanta, GA.
- The Use of Oxygen Treatment for Enhanced Wound Healing. Estridge T, Feldman D, poster presentation at 1991 Annual Meeting of the Federation of American Societies for Experimental Biology, Atlanta, GA.

[533] Analytical Service Demonstration of the Role of Biochemical and Behavioral Indicators in the Prevention of Recurrent Pressure Sores

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Sponsor: National Institute on Disability and Rehabilitation Research

Purpose—Our purpose is to confirm the potentiality of a biochemical indicator to predict skin breakdown and the efficacy of specific self-directed behaviors to prevent recurrent pressure sores.

Methodology—This is an observational, prospective, cohort study. Males with spinal cord injury are randomly assigned to two groups. The control group will be interviewed only at the beginning and at the end of the study and will provide a 24-hour urine sample at each of those times. The experimental group will be interviewed in person initially and then by telephone every 4 to 6 weeks. They will provide a 24-hour urine sample at the time of each interview. Follow-up will continue for 2 years or until the subject develops a pressure sore, whichever comes first.

The interviews will elicit demographic information, medical history with special emphasis on incidence of pressure sores, and a description of the usual skin care regimen. The urine will be assayed for the content of glucosyl-galactosyl hydroxylysine, a collagen metabolite.

The data analysis will seek to establish the relative risk of developing a pressure sore based on the fluctuations in urinary concentration of the collagen metabolite and/or specific items in the skin care regimen.

Progress—Data acquisition is almost complete.

There are 40 experimental and 20 control subjects. Compliance has been excellent. The most frequently cited pressure ulcer prevention methods were: weight shifts, not sitting too long, skin inspection, and using the proper cushion. Initially, 83% of the subjects believed they were not likely to develop a pressure ulcer within the year. At this time 28% of the subjects have developed a pressure ulcer. Incidence of pressure ulcers is almost the same among control and experimental subjects. Subjects with ulcers tend to be younger and to have lower body mass index. Mean time to appearance of a pressure ulcer has been 11 months. Urinary excretion of glucosyl-galactosyl hydroxylysine increases before clinical manifestations of a pressure ulcer are apparent. Statistical analysis of the data is under way.

Implications—Successful completion of this research project will provide a means of identifying patients at imminent risk of developing a pressure sore. More aggressive preventive measures can then be brought into play to forestall an actual skin breakdown. This should translate into a considerable reduction of hospitalization time and costs.

Recent Publications Resulting from This Research

Analysis of Pressure Ulcer Incidence in a Cohort of Spinal Cord Injury Men Followed Prospectively. Rodriguez GP, Garber SL, Arch Phys Med Rehabil 71(10):826, 1990.

[534] Treatment of Pressure Ulcers by Electrical Stimulation

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Purpose—The enhancement of pressure ulcer healing by direct current (DC) stimulation in a pig model has been reported. The current study compares the

healing effect of direct current with that of alternating current (AC) stimulation on pressure ulcers using the pig model.

Methodology—Twenty mini-pigs (5 AC, 5 DC, and 10 controls) were used in this study. Trochanteric pressure ulcers were created 2 weeks after right unilateral extradural rhizotomies from L1 to S2. Electrical stimulation was applied to the periphery of wounds for 2 hours per day. Changes in wound area and volume were obtained from photographs and direct measurement to estimate the healing rate. Biopsies were also obtained from the wound margin at weekly intervals for the histomorphometric analysis of the vascularity of the healing tissues. The number and size of the blood vessels were measured and analyzed using ANOVA. The change in area and volume constants were calculated by fitting the measured wound area and volume to an equation of exponential form.

Results—The area time constant was 9.4 ± 2.5 days in the AC group, 9.7 ± 3.1 days in the DC group and 13.5 ± 7.5 days in the control. The volume time constant was 4.0 ± 0.6 days in the AC group, 5.3 ± 2.5 days in the DC group and 5.1 ± 2.3 days in the control. From histologic slides, a significant

increase ($p < 0.05$) in blood vessel density was seen in the stimulated healing tissues, the number of blood vessels increased from $9.4 \pm 3.1/\text{mm}^2$ in the control to $21.6 \pm 8.0/\text{mm}^2$ in the AC group and to $19.2 \pm 8.2/\text{mm}^2$ in the DC group.

Implications—Both AC and DC stimulation appear to enhance the healing of pressure ulcers by reducing wound area and increasing vascular density of the healing tissues.

Recent Publications Resulting from This Research

An Experimental Pressure Sore Model for Functional Electrical Stimulation Continuous Pressure Application on Monoplegic Pigs. Negami S, et al., in *Advances in External Control of Human Extremities*, 535-541, DB Popovic (Ed.). Yugoslavia: Nauka, 1990.

Wound Healing and Perfusion of Pressure Ulcers in Direct Current Stimulated Denervated Tissues. Reger SI, et al., in *Advances in External Control of Human Extremities*, 525-534, DB Popovic (Ed.). Yugoslavia: Nauka, 1990.

Enhanced Neovascularization of Healing Pressure Sores with Electrical Stimulation. Reger SI, et al., in *Proceedings of the 14th Annual RESNA Conference*, Kansas City, MO, 1991.

[535] Pressure Sore Prevention: An Effective Stepped Care Approach

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Purpose—The goals of this project include the refinement, validation, and dissemination of a novel system with unique potential to produce durable preventive behavior and thereby lower the incidence and severity of ischial pressure sores. Its promise lies in its self-correcting, data-based approach; in its stepped, systematic application of a variety of interventions, both established and new; and in its utility in validating any effort at teaching pressure relief behaviors. The key to the system is the Timer-Logger-Communicator (TLC), an electronic device developed by the researchers. The TLC continuously and unobtrusively records pressure relief behavior, and provides data, cues, or immediate feedback to enhance pressure relief behavior.

Progress—We have completed collecting the data. We are now reducing the data to summaries and preparing the summaries for further analysis. Overall, we will continue to focus on analyzing data and preparing the TLC system for marketing. We have reviewed the TLC hardware. Since the device was designed, significant advances in electronics have been made. While going through another development cycle to take advantage of these new technologies is impractical, some of them may be easily implemented before commencing TLC manufacturing. Therefore, we will prepare the TLC for review by the engineering staff of a manufacturer.

Future Plans—A major ongoing activity is testing and revising the software to insure rapid, user-friendly, accurate operation. In addition, we are modifying the software so that the daily TLC report will be produced by a dot-matrix printer rather than by a plotter. This change will speed up the process of data analysis for clinicians and eliminate an expensive item of equipment. We are changing the

immediate feedback and avoidance programming to allow greater clinical flexibility.

Recent Publications Resulting from This Research

Precision Rehabilitation: Computerized Decision Support for the Clinician. Merbitz CT, in Proceedings of the Seventeenth Annual Convention, Association for Behavior Analysis, Atlanta, GA, 146, 1991.

[536] Interpreting Skin Redness as an Indicator of Early Pressure Sore Onset

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Sponsor: *Spinal Cord Research Foundation*

Purpose—Pressure sores have long been a complication of spinal cord injury and frequently result in serious tissue damage and prolonged hospitalization. The purpose of this study is to improve the understanding of the physiological changes in the skin that precede the onset of a pressure sore. One technique used by nurses and disabled people to detect early onset of tissue distress is the frequent observation of skin color, specifically prolonged or persistent redness over a bony prominence. Frequently they “blanch” the area by pressing the skin momentarily and then observe the time taken to return the red coloration. Fast recoloration is indicative of tissue distress, often referred to as a “stage 1” pressure sore. This clinical indicator is highly subjective, is difficult to use, especially for black patients, and its physiology is poorly understood.

Methodology—The proposed study will be con-

ducted in two phases. In Phase 1 we will undertake a comprehensive examination of the physiological changes associated with prolonged tissue ischemia. This information will be used in Phase 2 to establish specifications for the design of a simple-to-use clinical instrument. A laser Doppler flowmeter and a tissue spectrophotometer, both of which are non-invasive, will be employed to measure how fast blood flows in the vessels, the amount of blood contained in the area, and how much oxygen is supplied to the skin. Measurement of these three parameters is essential for the evaluation of peripheral blood circulation. In Phase 2 an instrument will be designed, developed, and tested. The instrument will measure key physiological changes identified in Phase 1 associated with the visual observation of skin redness clinically. The outcomes of this study will provide the clinician and patient with a more objective tool for the identification of “stage 1” pressure sores.

[537] A Program to Motivate Correct Skin Care in Persons with Spinal Cord Injury or Disease

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Sponsor: *Education and Training Fund, Eastern Paralyzed Veterans Association*

Purpose—Pressure sores have traditionally been a serious problem for persons with spinal cord injury and disease because of their negative consequences

on the individual's health, functional ability, and psychological well-being. The purpose of this program (Skin Care Educational Program) is to teach

individuals how they can be effective managers of skin care, regardless of degree of disability. Education programs for spinal cord impaired persons have been deficient by not emphasizing the individual's abilities in independent skin care management. Traditional programs have also not been evaluated systematically. Researchers have begun to recognize that a person's degree of motivation to take charge of skin care is related to the rate of pressure sore occurrence and to his/her eventual participation in social and vocational activities.

Methodology—The proposed project, the Skin Care Education Program, is a motivational and educational program for spinal cord impaired persons. The program's positive philosophy is demonstrated by several media and by repeated practice of good

skin care behaviors which convey personal efficacy to the individual. Good skin care habits which are associated with successful accomplishments in life-long endeavors are developed during inpatient hospitalization. The effectiveness of the Skin Care Education Program will be demonstrated through the participants' integration of material, observed practice of learned behaviors, and the degree to which they express confidence in their abilities to independently manage their own skin care. The proposed project will be disseminated by training new course instructors and by in-service programs to the direct care staff of Rusk Institute. The effectiveness of these dissemination activities will be evaluated in terms of the increased numbers of spinal cord impaired persons trained by the new instructors and by staff evaluations of the in-service programs.

B. Fracture Healing

[538] Comparison of Events in Bone Healing Influenced by CCEF and PEMF Signals

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Sponsor: VA Rehabilitation Research and Development Service (Project #A623-RA)

Purpose—Endogenous electrical changes associated with musculoskeletal injuries and the demonstrated osteogenic effects of exogenous electricity suggest that bioelectricity may have a fundamental role in fracture healing. However, some questions regarding the efficacy and time of application of various exogenous signals and the predictability of outcome remain to be answered. Development of an adequate mechanistic basis for electrotherapy in fracture healing may help to determine the conditions under which it can be a safe, reliable, and economical alternative to bone graft surgery. The purpose of this project is to evaluate and compare the effectiveness of two signals—capacitively coupled electric field (CCEF) and pulsed electromagnetic field (PEMF)—applied during the premineralization and early mineralization phases of fracture healing in an experimental model.

Methodology—The experimental model is a canine ulna in which a 1-cm segmental defect is created by transverse osteotomy followed by internal transfixation of the ulna to the adjacent radius with four Steinmann pins. The methodology is designed to test the following hypothesis: Electric field signals stimulate healing in delayed-healing fractures by inducing cell proliferation and, subsequently, synthesis of a matrix which is capable of ossification. A corollary hypothesis is that these signals have no direct effect on the process of mineralization. To test these hypotheses for CCEF and PEMF/EF (i.e., electric field component of PEMF), we apply each signal in separate groups of animals as follows: in one group the signal is applied during the premineralization phase only (0–3 weeks post-osteotomy) and in another group during premineralization and early mineralization phases

(0-7 weeks post-osteotomy) of healing of osteotomized canine ulna. The healing response is evaluated by determining the effects of each signal on 1) cell proliferation and matrix synthesis, and 2) matrix mineralization that leads to enhanced bone healing. For each stimulation protocol, the results for the CCEF signal are compared with those for PEMF/EF to determine whether one signal might be more effective than the other in different phases of healing.

Progress—Work is in progress to: 1) establish the baseline data for time-dependent changes in cellular and matrix parameters in the repair tissue by measuring these in tissues excised post-mortem at different times during 1-10 weeks post-osteotomy from animals not subjected to electrical stimulation; 2) finalize the procedure for the weekly monitoring and adjusting of the signal applied to the animal; and, 3) construct the additional electrical stimulation units and electrode packs needed for the first year of the project.

[539] Enhancement of Union in Segmental Defect Fractures with the Use of Ilizarov Distraction Osteogenesis and Dynamized External Fixators

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Sponsor: VA Rehabilitation Research and Development Service (Project #A278-2RA)

Purpose—The primary objective of this research program is to improve reconstructive surgery of diaphyseal segmental defect fractures (SDF) by enhancing fracture callous formation and proliferation. We are currently investigating some clinically relevant questions concerning 1) the use of mechanically induced distraction osteogenesis (Ilizarov procedure) to create vital lamellar bone, thus obviating the need for secondary harvesting of cancellous bone graft (CAN), and 2) the efficacy of utilizing controlled axial micromotion in promoting callous formation in healing SDF. By provision of mechanical stimuli to the fracture callous and by formation of constantly tubular bone able to withstand normal mechanical forces early on, DEF and Ilizarov techniques, respectively, help to avoid osteopenia, nonunion, and refracture that are prone to occur with conventional rigid external fixators. These studies, therefore, will be directly applicable in the orthopaedic clinic.

Progress—Our group has completed a study in which we developed a dynamized external fixator (DEF) which takes advantage of the subject's normal ambulatory activity to generate axial micromotion at the healing fracture callous site and allows investigator control of stress and strain levels within the healing defect. By manipulating these factors and optimizing timing of application, we are

determining the mechanical stimuli necessary for optimum osteogenic environment, thereby developing a degree of control over healing of the fracture callous. With this information we are developing a model of fracture callous healing behavior defining the relative contribution of temporal and mechanical stimuli.

We are currently analyzing radiographic, histomorphometric, and biomechanical data from completed Ilizarov studies in order to better understand this tensile-force-induced membranous ossification process.

Methodology—Our studies center around the use of our canine bilateral radial defect model in which each animal acts as its own control.

In DEF experiments, a 2.5 cm defect is created in both legs and supplanted with CAN. With our DEF we alter spring stiffness (stress), degree of axial movement (strain), and time frame of application. In Ilizarov studies, a 2.5 cm defect is created in one leg and a corticotomy performed to create a 2.0 cm transport segment. Distraction is accomplished via wires attached to screws implanted in the transport segment and running subcutaneously in an axial direction before exiting distally to ratcheting tensioning clamps attached to an external fixator. The transport segment is moved following a 1-week

latency period. Laser doppler flowmetry is utilized to study neovascularity during transport.

In all studies, biomechanical (impact torsional testing), radiological, and histomorphometrical parameters are extensively studied.

Results—We have demonstrated the feasibility of the Ilizarov procedure for healing SDF. Optimum segment transfer rate was found to be -1.0 mm/day. We also determined the most effective technique and wire tension for guiding the segment to assure “docking” at the distal portion of the bone.

When using the DEF our results indicate that at an interfragmentary strain of -8% and a load equivalent to 10% of the subject's bodyweight at a constant compressive deformation of 1.0 mm, ani-

mals receiving a DEF 3 weeks post-surgically show significantly increased biomechanical strength parameters compared with animals receiving a DEF on the day of surgery.

Future Plans—Our group proposes to perform distraction osteosynthesis over an intramedullary biodegradable poly L-lactic acid rod providing guidance and interim fracture stability. This rod would gradually degrade while incrementally transferring stress to the bone and would allow reconstitution of normal intramedullary cavity contents.

Data from the DEF studies will be used to develop a predictive finite element model of stresses within the fixator-fracture callous unit and when combined with the experimental model will aid in designing a DEF of “ideal” strain and stiffness.

[540] In Vivo Experimental Approaches for Relating Tissue Differentiation to Mechanical Loading History

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Sponsor: VA Rehabilitation Research and Development Center (Core Funds)

Purpose—The purpose of this work is to elucidate the effect of mechanical stimuli on the proliferation and differentiation of cells during connective tissue regeneration in fracture healing. In this study we conduct a controlled, *in vivo* experiment to determine the role that mechanical stress and strain have during this process.

Methodology—A surgical procedure on rats was developed, and two sets of implants with slightly different designs were created. During surgery, a 5 mm section was surgically removed from the mid-shaft of a rat fibula. An implant with a cup-shaped end was inserted in the space formerly occupied by the fibula, such that the cup was positioned over the distal fibula stump. Differing fixation schemes were employed such that “experimental” cups would have one degree of freedom and would move significantly relative to the fibula stump during normal rat locomotion, while “control” cups would have no degree of freedom, and would remain relatively fixed.

Twelve operations have been performed, with seven rats receiving the experimental implant and five receiving the control implants. The rats were returned to their cages for 6 days to recover from the surgery, then were transferred to a wheel cage which recorded voluntary walking or running activity. Three weeks following surgery, the rats were sacrificed and their legs were immediately removed at the knee and fixed in formalin. The implant and surrounding tissue was analyzed histologically. Tissue differentiation patterns were compared with the stresses and strains that the tissue experienced, as calculated by a three-dimensional computer finite element model.

Preliminary Results—Eight of the operations done to date have resulted in successful implantation of the cup. In general, experimental cups were incompletely filled with fibrous tissue. The control cups were lined with newly formed cartilage such that the fibula stump resembled a joint surface. The cups that were associated with inflammation, whether

experimental or control, were never associated with bone or cartilage formation.

Based on the histologic analysis to date, a few preliminary conclusions can be drawn: 1) Inflammation inhibits bone and cartilage formation. 2) Large tissue distortional strains, associated with significant cup movement, appear to cause fibrous tissue formation and inhibit connective tissue precursor cell migration. 3) Low tissue distortion appears to be permissive for the development of bone and cartilage. 4) Cartilage formation at the cup edge in control cups may be associated with locally decreased oxygen tension. This would be caused by the diffusion barrier that the cup creates, and possibly

from increased hydrostatic pressure in that area.

Future Plans—More experiments will be done to confirm the results of this study. Tentative plans call for a reevaluation of the surgical procedure to increase the percentage of successful operations, and for the development of a system which will monitor and verify the movement of the cup implant *in vivo*. It is hoped that with the results of this study, a better understanding of the mechanical effects on connective tissue differentiation will result in improved treatment of fractures and increased success rates for joint replacement prostheses.

[541] Biomechanics of External Fixation of Tibial Fractures

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Sponsor: Orthofix Srl., Verona, Italy; Scottish Home and Health Department

Purpose—External fixation is a method of managing tibial fractures which offers the potential for studying and controlling the biomechanical environment in which the fracture is maintained. The aim of this project is to measure how this biomechanical environment changes as the fracture heals, to determine how this information can be used clinically, and to develop a system which can perform these measurements in a routine clinical environment.

Methodology—A strain-gauged transducer has been built into the fixator body to measure the six components of force and moment which it carries. Externally applied (ground reaction) forces and moments are measured using a Kistler force plate. Use of a VICON kinematic analysis system allows the effect of these forces at the fracture site, and hence the ratio of shared loading between the fixator and healing bone, to be estimated. The data is analyzed for changes occurring through healing, and these are correlated with radiological and clinical observations.

A modified system has been developed to measure those parameters which have been of most

potential for clinical monitoring of fractures (vertical component of ground reaction and axial and two bending moment components of the load carried by the fixator) based on a personal computer.

Progress—The initial system has been developed and is capable of giving estimates of the six components of load carried by the fixator, and applied externally, during standing, walking, and certain clinical tests. Twenty patients have been monitored from initial application of fixator through to removal.

The clinical measuring system has been fully developed and has been used to monitor two patients from application through to clinical union.

Preliminary Results—Several trends are suggested by results to date. Changes in the ratio of shared loading of the axial components of force give an early indication of the stability of the fracture and can be used to help determine the appropriate timing for dynamization. Changes in the ratio of shared loading of bending moment components are observed later in the healing period and can give an

indication of appropriate timing of the removal of such devices. Regular monitoring can give an early indication of pathological healing patterns.

These patterns appear to be monitored by the personal computer-based system which has been developed.

C. Other

[542] Artificial Nerve Graft: Union of Cellular and Noncellular Components

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Sponsor: VA Rehabilitation Research and Development Service (Project #B588-RA)

Purpose—After peripheral nerve injury, it is frequently impossible to achieve end-to-end anastomosis despite extensive mobilization and re-routing of surviving nerve. Autografts yield acceptable recovery of sensory and motor function, but are limited in availability and entail donor site surgery.

The goal of this project is to improve the results of nerve repair by developing a multicomponent artificial nerve graft (ANG). The proposed artificial nerve graft is composed of a passive conduit made of glycolide trimethylene carbonate (GTMC) and a medium consisting of oriented collagen and cultured Schwann cells.

Methodology—The experimental model consists of a 10 to 15 mm gap in the rat peroneal nerve. Short-term (3 mo) animals are evaluated by qualitative histology only, while long-term (12 mo) animals are evaluated noninvasively every 2 months via walking pattern (toe-spread) analysis (functional test) during the regenerative period and with qualitative histology, transmission electron microscopy, fiber diameter histogram (quantitative histology), electrophysiology and twitch-tension analysis (functional test) at the end of the regenerative period.

Progress—Schwann cells are obtained from neonatal Fischer rats, from which dorsal root ganglia (DRGs) and sciatic nerve explants are obtained. In order to improve the quantitative yield of Schwann cells and their rate of proliferation, we are exploring alternative isolation methods based on substrate affinity

rather than immunochemical lysis. Several procedures for forming flat sheets and tubes of cell-containing collagen are being explored. We also use a simplified method of mixing cells and collagen immediately before injection into a tube, which results in a homogeneous sponge-like network; this method has been used on all implanted ANGs to date.

It has proved necessary to more rigorously characterize the properties of tubes used to fabricate the grafts. This is done by: 1) porosity assay, consisting of sealing of molecular weight standards inside short lengths of tube and incubation in phosphate-buffered saline; and 2) cantilever bending, a nondestructive test to reveal changes in material stiffness and dimensions between batches and over the course of incubation.

Seven groups of rats have been implanted with ANGs. In addition to GTMC tubes, we have tested collagen-fibrin tubes supplied by the University of Utah and elastomer-hydrogel tubes made by Menlo-Care, Inc. Both types are semipermeable, which GTMC is not, thus allowing diffusion of nutrients to support the Schwann cells through the walls of the tube as well as through the ends. Repeated walking track analysis has shown that Schwann-cell-containing ANGs are superior to collagen-only ANGs, which in turn are superior to empty tubes. End-point tests (histology and electrophysiology) are incomplete at this point.

Preliminary Results—A new organ culture technique has been devised to simulate the *in vivo* situation in

which axons penetrate and elongate through the lumen of the ANG. A neonatal rat DRG is placed into one end of a 5 mm GTMC tube and provides a source of neurons (as well as fibroblasts, unless specific measures are taken to remove them). In one experiment, a homogeneous collagen Type I matrix

was compared with coating the inner wall of the tube with either collagen or collagen plus laminin. Still and video photography demonstrated both stromal and neural tissue elongation down the length of the tube, with laminin stimulating more rapid growth.

[543] Diabetic Foot Ulcers: Risk Factors and Pathophysiology of Wound Repair

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Sponsor: VA Rehabilitation Research and Development Service (Project #A318-3RA)

Purpose—This study will accomplish concurrently two separate but related goals pertinent to limb preservation in diabetes: first, the identification and quantification of risk factors for foot ulcers associated with diabetes; and second, clarification of the pathophysiology of local cutaneous circulation responsible for wound healing failure. Major hypotheses will be: 1) there are pathophysiologic conditions, anatomic features of the foot, and lifestyle or self-care behaviors of diabetic individuals that will predict the development of foot ulcers and the respective relative attributable risks can be quantified; and, 2) the rate of healing of cutaneous ulcers in diabetes depends on the adequacy and reserve capacity of the local cutaneous capillary circulation.

Methodology—Using a prospective cohort design, we will study 720 diabetic subjects recruited from among regularly scheduled patients in a large general internal medicine clinic, document potential risk factors for foot ulceration during a thorough intake evaluation, and follow those patients prospectively in order to identify subjects who acquire foot ulcers. Potential risk factors will be documented by physical examination; directed medical history; clinical testing of biomechanical, neurologic and circulatory parameters; and a standardized neurovascular laboratory evaluation, including determinations of autonomic function, aesthesiometry, segmental Doppler blood pressures, transcutaneous oxygen tension, and capillary flow by laser Doppler velocimetry.

In a concurrent but separate protocol, those study subjects who acquire foot ulcers requiring medical treatment during the follow-up surveillance period will be recruited at that time for specific biomedical studies of wound healing. These studies will detail the critical importance of local periwound cutaneous circulation to wound healing.

Preliminary Results/Implications—Preliminary results will not be available until at least 2 years of data collection has occurred and appropriate preliminary analyses have been done.

Lower limb amputation in diabetes represents a major adverse outcome that affects many individuals with diabetes (estimated to be 60,000 lower extremities per year). Over 80% of lower limb amputations are preceded by nonhealing ulcers of the foot. Effective treatment and prevention depends on better understanding of the critical risk factors for foot ulceration and wound healing failure in patients with diabetes.

Recent Publications Resulting from This Research

Outpatient Management of Uncomplicated Lower Extremity Infections in Diabetic Patients. Lipsky BA, et al., *Arch Intern Med* 150:790-797, 1990.

Pathways to Diabetic Limb Amputation. Basis for Prevention. Pecoraro RE, Reiber GE, Burgess EM, *Diabetes Care* 13:513-521, 1990.

The Chronology and Determinants of Tissue Repair in Diabetic Lower Extremity Ulcers. Pecoraro RE, et al., *Diabetes* (in press).

XVIII. Miscellaneous

[544] Predicting Wayfinding Ability from Laboratory-Based Spatial Tasks

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Sponsor: *VA Rehabilitation Research and Development Service (Project #D525-RA)*

Purpose—The primary goal of this 3-year study is to ascertain whether measures of microspatial (tabletop tests) abilities are related to wayfinding abilities in macrospatial (real world) environments. Relevance of this question to the Department of Veterans Affairs lies in the fact that many disabled veterans, such as those who are elderly or have sensory or cognitive deficits, may experience problems in mobility and spatial cognition. The ability to accurately identify handicapped individuals at risk for disorientation would ultimately facilitate intervention in spatial orientation. Relevance to the Department of Defense lies in the fact that many military activities, such as aviation and troop movement, require good spatial orientation, wayfinding, and map reading skills in unfamiliar and adverse situations. If measures of “tabletop” or paper-and-pencil spatial abilities correlate moderately or well with large-space wayfinding, then it may be possible to use microspatial tasks for screening and selection of military personnel for jobs requiring a high degree of spatial ability.

Methodology—To complete this research, subjects ranging in age from 18–25 years are given a battery of “tabletop” or paper-and-pencil tests, from the Kit of Factor Referenced Cognitive Tests, which measure various aspects of this complex behavioral domain (e.g., spatial visualization, memory for spatial information, spatial closure). They also perform a set of tasks, which involve viewing a

5 × 7 ft model town, and respond to questions which measure perspective verification and map verification. Finally, subjects walk predetermined routes inside a building and out-of-doors in a residential area. After these walks, subjects perform tasks which measure general euclidian orientation, feature recognition, temporospatial ordering of landmarks, map placement of landmarks, and route reversal. Data analysis involves multiple regression analyses in which measures of macrospatial ability serve as the criterion variables and psychometric and experimental tasks serve as predictors.

Progress—Data have been collected on a total of 177 subjects to date. Preparation of these data for analysis is being performed at present. Data were collected through the end of December 1991.

Results/Implications—This study will identify which types of microspatial tasks show a valid and reliable relationship to selected macrospatial tasks, and the magnitude of those relationships. It may be possible, for example, to use the findings as a basis for the establishment of norms for spatial behavior across age. These data would help in determining the differential effect of normal aging and sensory or cognitive decline as they affect spatial behavior. It may also be possible to extend this work to the identification of compensatory strategies which can be taught to civilians and military personnel in need of enhanced mobility or wayfinding skills.

[545] Prevention of Immunologic Rejection of Tissue and Limb Allografts

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Sponsor: VA Rehabilitation Research and Development Service (Project #A618-RA)

Purpose—The purpose of this study is to overcome the immunologic rejection mechanism in order to transplant highly immunogenic tissue, such as skin, bone, nerve, and composite tissues such as vascularized whole joints and limbs. Existing treatments for induction of nonresponsiveness to transplants are unacceptable because of their significant morbidity, which is only acceptable in treating life-threatening disease.

Progress—The effects of immunization with modified transplantation antigens were studied with or without the concurrent use of new immunosuppressant drugs in models of allograft rejection in the rat, dog, and human to clarify mechanisms by which sensitization or induction of nonresponsiveness/tolerance occurs.

Methodology—For studies in humans, B lymphoblastoid cell lines from normal blood donors which have had HLA-A2 or HLA-B27 transfected and expressed in them are being used. These reagents are used to test the target antigens and the inducers of T suppressor cells generated in mixed leukocyte culture (MLC) with human lymphoid cells under conditions where the target antigen is precisely defined. In the rat model, we have three end points. These are: 1) the *in vitro* lymph node MLC responses; 2) histoincompatible skin graft survival; and, 3) hind limb allograft survival. In the dog, the bone marrow transplant model is utilized to assess the effects of transfusion from donor animals into recipients followed by marrow grafting from the donor animal. This allows determination of the effects of modifications of the transfusion product on graft outcome. We use either DLA-identical littermates to measure sensitization to minor histocompatibility antigens or DLA non-identical dogs to examine the effects of major DLA transplantation antigen differences on graft outcome.

Results—Studies on the HLA-transfected human lymphoblastoid cell lines have demonstrated that these cell lines express the new HLA antigens. These cells have been used to stimulate blood cells from normal individuals in mixed lymphocyte culture. We are optimizing the assay for generation of suppressor cells for analysis of antigen dominance in terms of a) generation of suppressor cells, and, b) in terms of target specificities. Also, normal families are being recruited for the studies so that we can determine whether or not there is any effect of prior *in utero* exposure to maternal HLA antigens which might alter immunologic responsiveness to these antigens in adult life.

In the rat model, minor reductions in recipient anti-donor MLC responses were found after one donor-specific transfusion. After three donor-specific transfusions, there appears to be enhanced cellular activity *in vitro*. We have demonstrated that donor-specific transfusion given with the immunosuppressant FK-506 markedly enhances survival of skin transplants compared with either treatment alone. In addition, survival of totally histoincompatible hind limb allografts is also markedly facilitated by treatment with FK-506, with a significant number of animals having transplants surviving greater than 60 days. Analysis of rats with long-term hind limb allograft survival has demonstrated decreased cellular immune responsiveness of lymph node cells of recipients against donor antigen both in mixed lymphocyte culture and in limiting dilution analysis.

In the dog model, it was shown that modification of blood transfusions prevents sensitization to *minor* transplant antigens. Treatment of transfusions with either heat and gamma radiation, or UVB and gamma irradiation, or with gamma irradiation alone prevents those transfusions from sensitizing recipients to subsequent marrow transplants from the donors of the blood product. Experiments on

the effects of these methods of modification of transfusions in terms of prevention of sensitization and/or induction of tolerance to *major* histocompatibility complex transplant antigens are underway.

Future Plans/Implications—The synergistic effects achieved with FK-506 are highly encouraging. We will optimize suppressive regimes and conditioning for highly immunogenic skin grafts and apply them to the limb allograft model. Finding that low dose gamma radiation abolishes sensitization to minor histocompatibility antigens in this dog marrow transplant model is new and suggests that human

blood products should be gamma irradiated to prevent sensitization to minor antigens.

Recent Publications Resulting from This Research

Treatment of Marrow Donor Blood Products with Gamma-Irradiation Prevents Transfusion-Induced Sensitization to DLA Identical Marrow Grafts. Storb R, et al., Trans Proc 23:1697-1698, 1990.

Gamma Irradiation of Marrow Donor Blood Prevents Transfusion-Induced Sensitization to Minor Histocompatibility Antigens on DLA-Identical Canine Marrow Grafts. Bean MA, et al., Transplantation (in press).

Synergistic Effect of FK-506 and DST on Rat Skin but not on Composite Tissue (Limb) Allograft Survival. Kuroki H, et al., Trans Proc (in press).

[546] Design of a Radiotranslucent Chair for X-Ray Analysis of Dysphagia

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Sponsor: VA Rehabilitation Research and Development Unit (Core Funds); American Legion

Purpose—The purpose of this pilot study is to develop a radiotranslucent chair for use in x-ray analysis of patients with dysphagia. Many stroke, spinal cord, and cancer patients have problems swallowing after medical onset. The rehabilitation therapy regimen for these patients is best determined by an analysis of their swallowing pattern, which is often based on a fluoroscopic exam. Unfortunately, many of these patients cannot stand, or even sit upright, and metal wheelchairs interfere with the x-ray exam.

Progress—A survey of existing x-ray equipment was completed to determine the maximum space between the x-ray head and the table. The patient seated in the chair must fit into this space for anterior-posterior and lateral views. These data provided critical dimensions. A mock-up chair was constructed from fiberglass, and evaluated by the Radiology and Speech Pathology staffs at three different medical facilities. It was recommended that the chair shoulder dimensions be changed to more easily accommodate different types of x-ray equipment. It was also recommended that the headrest be adjustable in three planes to accommodate those with severe swallowing problems.

Methodology—Designing a radiotranslucent chair was not as simple as envisioned. The need for adjustment and wheeled mobility led to the following design criteria:

1. Chair frame can mount to existing side rails of metal wheelchair, with the back-rest supports removed
2. Chair frame can mount to center pedestal, such as on powered scooters
3. Chair frame material is radiotranslucent (no grain or fibers)
4. Chair frame is covered with foam-backed vinyl to sanitize easily
5. Arm rests are removable and adjustable in height
6. Seat height is easily adjustable with patient seated
7. Restraint straps are in appropriate positions to stabilize the patient
8. The chair frame material and design accommodate an easy manufacturing process to keep costs reasonable.

Results—The prototype chair has been modified to change the upper dimensions. The addition of the adjustable head rest will be deferred to later models, if a need is demonstrated. An x-ray manufacturer

has been contacted to determine its interest in adding this chair as an accessory unit for its x-ray

equipment. The chair is being evaluated at other facilities to ensure its universal utility.

[547] Integrating Trauma and Rehabilitation (ITR)

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Sponsor: Centers for Disease Control

Purpose—This 3-year study has two purposes. The first is to link 308 patient records from two national data bases with overlapping patient populations from trauma care and rehabilitation. These records will be used to develop a patient injury and functional profile from time of injury to discharge from medical rehabilitation. The second is to identify and interview 158 brain-injured patients who did not receive medical rehabilitation services but are matched with those who did receive rehabilitation. The results of the study will contribute to the design of a model trauma registry program that will be responsive to the rehabilitation needs of seriously injured patients.

Progress/Methodology—The patients for this study come from a national trauma data base known as the Major Trauma Outcome Study (MTOS) and from a national rehabilitation data base known as the Uniform Data System (UDS). Since these data bases do not contain names or personal identifiers, the linking of patient records from these data bases is being facilitated through the cooperation of local trauma centers and rehabilitation centers. The study methodology is specifically designed to preserve

patient confidentiality. The target impairment groups for this portion of the study include traumatic brain injury, spinal cord injury, and hip fracture.

Some 158 brain-injured persons, who received rehabilitation and were located through the linking portion of the study, will be matched with persons in the trauma data base who did not receive rehabilitation. These individuals will be interviewed to determine why they did not receive rehabilitation and to make a preliminary assessment of any differences in long-term outcome.

During its first year, the study has identified and recruited a number of trauma and rehabilitation centers that are most likely to have overlapping patient populations. A full-scale linkage methodology has been developed and is being implemented in local sites.

Future Plans/Implications—In the coming year the study will complete the linking portion of the study and will design/implement the matching portion of the study. The study has important implications for overcoming the discontinuities that now exist between trauma care and rehabilitation.

[548] National Invitational Conference on the Development of a Health Services Research Capacity in Physical Disability and Rehabilitation

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Sponsor: National Institute on Disability and Rehabilitation Research

Purpose—The purpose of the conference was to gather an invited group of 70 experts in the fields of trauma care service delivery, the organization and financing of rehabilitation services, personal assistance services, and long-term institutional care

services, to identify significant research topics and a specific research agenda for consideration by potential public and private funding sources. The proceedings of the conference are being disseminated to federal agencies and private foundations,

policy makers, payers, providers, researchers, and others.

Progress/Methodology—The conference was held on September 26 and 27, 1990. Invited participants were selected to represent the research, policy, consumer, and provider communities. James Mason, M.D., Assistant Secretary for Health, delivered the keynote address. He emphasized the demographics of the 43 million Americans with disabilities, the current activities in the Executive Branch and Congress relative to the health of disabled Americans, and the challenge of creating an agenda in health services research-related to the needs of people with disabilities.

The small-group workshop sessions on the four core topic areas of the conference—trauma care service delivery, the organization and financing of rehabilitation services, personal assistance services, and long-term institutional care services—were the heart of the conference.

Results—The conference resulted in a set of printed proceedings that can be obtained at the above-listed address.

Future Plans—The NRH Research Center will continue to work with NIDRR and other agencies in implementing the findings of the conference.

[549] Trauma and Disability Outcomes (TDOS)

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Sponsor: National Institute on Disability and Rehabilitation Research

Purpose—This study examines how the severity and prevalence of disability from traumatic brain and spinal cord injury changes affect the need for medical rehabilitation and various long-term care services. The study surveyed 427 traumatic injury survivors from 3 level-1 trauma centers, located at the Washington Hospital Center in Washington, DC; the University of California, San Diego; and the University of California, Davis, in Sacramento.

The study was designed to: 1) ascertain the long-term outcomes (up to 5 years) of trauma survivors; 2) determine the extent and correlates of rehabilitation utilization; and, 3) evaluate how injury acuity (e.g., as measured by the Revised Trauma Score and the Injury Severity Scale) relates to long-term outcome (e.g., as measured by various components of the Sickness Impact Profile).

Progress—All data collection has been completed and data analysis has been partially completed. Several manuscripts are currently in preparation for publication.

Methodology—Patients who experienced serious head or spinal cord injury treated in three major trauma centers during 1984-1989 were mailed ques-

tionnaires which solicited information on their physical and social functional status, rehabilitation experience, and general outcomes since their injuries. These data were combined with data on each patient from the Major Trauma Outcome Study (MTOS), a multi-institutional trauma data base sponsored by the American College of Surgeons. Combining these two data sources for the same patients enabled linking trauma acuity data with long-term outcome data for each patient.

Results—These data are being analyzed and focus on the interrelationship between injury severity, use of rehabilitation services, and functional outcome. This analysis includes an assessment of how injury severity and the receipt of rehabilitation services affect long-term outcomes. The study also investigates the ability of three injury severity measures (RTS, ISS, and probability of survival) to predict receipt of rehabilitation, and predict functional outcome.

Preliminary data reveal that 62% of the SCI respondents and 33% of the TBI respondents received inpatient medical rehabilitation. More severely injured patients tended to receive rehabilitation, as expected, and those who did receive rehabil-

itation exhibited correspondingly greater impacts on their lives from their injuries (as reflected by SIP scores).

Long-term disability was evident among the respondents. There was a marked change in employment status from injury to follow-up, and there were significant reductions in overall productivity for the sample. Respondents found significant lifestyle changes after injury—reduced participation in

social and sports events, and in driving for transportation.

Future Plans/Implications—The results of this study have implications for: 1) knowing how injury severity maps into long-term functional status; 2) identifying appropriate traumatically injured candidates for rehabilitation; and, 3) understanding the impact of trauma care on the need for rehabilitation and other long-term care services.

[550] Rehabilitation Technology Training: A Plan for Facilitating the Delivery of Technology

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—This project is one of three supported by the REC on Technology Transfer. The initial goal of this project is to investigate the technology training needs of occupational therapists and to develop a training program to address these needs. Training programs for other disciplines will be developed based on the results of the training for occupational therapists.

Progress—A needs assessment has been conducted to identify the training needs of occupational therapists in the area of application of assistive technology. A survey instrument was developed and mailed to 2,666 occupational therapists. The results indicated a perceived need for training in service delivery and in specific types of technologies. Of the service delivery needs, the most frequently identified were information resources, funding, and task analysis. Of the specific technology types, respondents identified training needs most frequently in the high-visibility and high-technology areas of equipment interface, environmental controls, and computers.

Based on this survey and suggestions from our Advisory Committee, a 2-day course entitled

“Adding Technology to Your Bag of Tricks” has been developed. The course has been pilot tested twice and has been revised based on this experience. The American Occupational Therapy Association (AOTA) will disseminate this program as one of their train-the-trainer courses. AOTA would also like to offer components of the workshop material to their members as a home study course. We have just begun to revise the course material so it is suitable for this format.

Future Plans—The goal for next year is to further develop the course material so it is more suitable for other professionals. A task force met in November 1991 to recommend changes that should be made. RESNA has already indicated an interest in sponsoring the course nationwide once it is ready for dissemination.

Recent Publications Resulting from This Research

A Survey of the Assistive Technology Training Needs of Occupational Therapists. Somerville NJ, et al., *Assist Technol* 2(2):41-49, 1990.

[551] Transferring Technology from the Research Laboratory to the Commercial Market

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—This project is one of three supported by the REC on Technology Transfer. The goal of this project is to provide assistance to investigators who are interested in transferring their research results to manufacturers and service providers. The activities described below have been pursued in the past year.

Progress—*Survey of commercialization activities of Rehabilitation R&D Centers.* A survey instrument was prepared and mailed to 20 centers that are involved in rehabilitation R&D. It asked questions about the organization of and decision-making processes within the REC, relationships with manufacturers, and the REC's experience with patenting, licensing, and royalties. A similar survey instrument was mailed to the NSF Industry/University Cooperative Research Center (IUCRCs). Results indicated that both RECs and IUCRCs are involved in commercialization, but RECs are typically more involved than are IUCRCs. The average REC has over 25 contacts with industry each year to discuss ideas for products and show off prototypes. While over half of the RECs have received royalties for products they have created, receipt of royalties is much less common among IUCRCs.

Techniques for commercializing research products. Material was prepared for a half-day course entitled: "I Have This Great Idea for a New Product! Now What Do I Do?" The course discusses topics such as protection, patenting, and evaluating commercial potential and leads the audience down two roads: one leading to a licensing agreement, the other to starting one's own business. The course has been presented at the RESNA Annual Conference. In the coming year, a booklet of the same name will be prepared and published.

Evaluation of UVA CAD/CAM seating systems. Rancho and the National Rehabilitation Hospital have organized and conducted a beta-site evaluation of a seating system developed by the University of Virginia. Pin Dot Products (Chicago, IL) is planning to market a version of this system and is providing custom cushions to study participants. The five sites participating in the evaluation are: Newington Children's Hospital, National Rehabilitation Hospital, Helen Hayes Hospital, Rancho Los Amigos Medical Center, and Texas Institute for Rehabilitation and Research. Results are currently being tabulated.

[552] Implementation and Follow-up of Rehabilitation Technology

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Sponsor: *National Institute on Disability and Rehabilitation Research*

Purpose—This project will test the hypothesis that the acceptance and successful use of rehabilitation technology is critically dependent upon the following factors: appropriate training in device use, adequate written instructions, and follow-up to determine the outcome of using the device. This project will be conducted at the Children's Hospital at Stanford, Palo Alto, California.

Progress—A literature search was completed to determine the type of follow-up programs that have been implemented in the field of assistive technology. As a result of the search it was noted that only a handful of centers in the U.S. that deliver assistive technology have attempted a follow-up program, and none of them had a documented approach that included a follow-up protocol. To tackle the issue of

following-up clients after they receive a piece of assistive technology, the Rehabilitation Engineering Center at Stanford identified two levels of follow-up care that were intended to increase the use, safety, satisfaction, and longevity of the device as used by the subject. These procedures included the use of videotape, phone calls, additional written directions, and home evaluations. Fifty-eight subjects were entered into the 1-year study during 1989-1991 and the subjects were randomly divided into three equal groups. One-third received the "customary" follow-up procedure (control group), one-third received a slightly increased level of follow-up (intermittent phone-calls; experimental group A), and the remainder were assigned to the third group who received the highest level of follow-up (phone-calls and videotape of their delivery session; experimental group B).

Future Plans—Those methods that best helped the subject incorporate the device into their daily lives are currently being implemented at four different assistive technology centers in California (Assistive Device Center; Rancho Los Amigos; Santa Clara Valley Medical Center; and Sharp Memorial Hospital). Once the four centers have completed the 6-month follow-up period on an estimated total of 120 subjects, the follow-up protocol will be made available for distribution.

Recent Publications Resulting from This Research

Is Technology Used/What Should We Ask To Find Out? Mortola PJ, Kohn J, LeBlanc M, Team Rehab Report, Jan./Feb. 1992.

A Follow-Up Plan for Rehabilitation Technology: An Occupational Therapist's Role. Mortola PJ, Kohn J, LeBlanc M, Int J Tech Assess Health Care, 1992.

[553] Electromagnetic Effects on Bone Tissue and Its Chemistry

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Sponsor: National Institute of Arthritis, Musculoskeletal, and Skin Diseases

Purpose—The overall goal of this research project is to determine whether alterations of the chemical and thermal environments occur *in vivo* during electrical and electromagnetic stimulation of osteogenesis—the growth of new bone. The effects of three different modes of electrical and electromagnetic stimulation on tibial osseous and medullary canal tissue will be investigated in three animal groups with rabbits employed as experimental subjects. The modes of stimulation are as follows: (Group I) faradic stimulation by controlled direct current with implanted electrodes; (Group II) faradic stimulation by controlled cathodic potential with implanted electrodes; and (Group III) inductive stimulation by rectangular waveform with external coil pairs. Alterations of the chemical (oxygen tension and pH) and thermal (temperature) environments are determined using microelectrodes or microprobes inserted through the tibial cortex into medullary canal tissue by means of a transcortical, silicone rubber implant positioned at the site of electrical or electromagnetic stimulation.

Methodology/Progress—The various circuits and appliances necessary to produce the three different modes of electrical and electromagnetic stimulation have been designed, tested, and evaluated. Each mode of stimulation involves different circuitry: faradic stimulation by constant direct current, faradic stimulation by controlled cathodic potential, and inductive stimulation by rectangular waveform.

In each animal, one tibia sustains active stimulation at the experimental bones while the contralateral tibia serves as the control with no stimulation. To permit appropriate comparisons among the different modes of stimulation, all animals sustain identical methodology and, thus, receive bilateral (a) transcortical silicone rubber implants which permit microelectrode or microprobe insertion into tibial medullary canal tissue; (b) coil pairs which are either active for inductive stimulation or inactive for all other techniques; and (c) intramedullary wires which are either metallic electrodes for faradic stimulation or polytetrafluoroethylene (Teflon™) beading to mimic elec-

trodes for inductive stimulation. Since rabbits exhibit seasonal differences and since personnel acquire experience over time, each experiment includes animals from different groups to insure that no single experiment involving a single mode of electrical stimulation is performed at any one time period or at any particular level of technical expertise.

Sixty rabbits have sustained a surgical procedure involving implantation of a transcortical, silicone rubber implant and insertion of either a metallic or polytetrafluoroethylene wire into the medullary canal of both tibiae. After a 4-week postoperative healing period, 48 of the 60 animals were judged to be physically capable of undergoing the subsequent 21 days of either electrical or electromagnetic stimulation. The electrical characteristics of the faradic and inductive stimuli were

recorded daily. Weekly measurements of pH, oxygen tension, and temperature within tibial medullary canal tissue at the site of stimulation were performed bilaterally in each animal under anesthesia. Upon completion of the treatment period, each animal was sacrificed and its tibiae were excised.

Preliminary Results/Future Plans—The tibial specimens are now being processed for histomorphometric analysis of the biological response to electrical and electromagnetic stimulation. Statistical analyses of the electrical characteristics of the faradic and inductive stimuli as well as the pH, oxygen tension, and temperature measurements performed *in vivo* will be conducted for subsequent comparisons to the osteogenic response presented within the rabbit tibial medullary canal tissue.

[554] Application of Microcomputer Alternate Access Methods to Music Composition and Education

Roger Knox, PhD; Fran Herman, MTA; Rebecca Loveszy, RMT
Hugh MacMillan Rehabilitation Centre, Toronto, Ontario M4G 1R8 Canada

Sponsor: *Social Sciences and Humanities Research Council of Canada; Ontario Ministry of Health, Neurodevelopmental Clinical Research Unit, Chedoke Hospital*

Purpose—People with disabilities can now participate in contemporary modes of musical expression with the aid of computer and sound synthesis technology. At the Hugh MacMillan Rehabilitation Centre (HMRC), the Microcomputer Applications Programme's research into alternative access methods has stimulated an interest in their appropriate use with music composition and educational software. Further, using the Musical Instrument Digital Interface (MIDI), both commercially available dedicated hardware and specially adapted controllers can interface with the computer, opening up many new musical possibilities.

Working with the Creative Arts Department of the HMRC, three components of music access are being evaluated: 1) software (music notation, sequencing, teaching, and other programs); 2) dedicated hardware (MIDI keyboard, drum pad, pitch-to-MIDI converter, and real-time arranger); 3) computer input devices in the context of their musical applications (headpointers, track balls,

mouth or foot switches, altered keyboards, and voice-input systems). The goal is to develop compositional and educational strategies appropriate for several disabled groups, beginning with head-injured adolescents. A multifaceted approach is employed in which musical, therapeutic, and technological considerations come into play, with an emphasis on creative song-writing and improvisation. In conjunction with the HMRC Psychology Department, the effectiveness of electronic music in cognitive retraining for head-injured adolescents is being studied, with the specific area of attention enhancement chosen for research. Consultation on computers in music has also been provided to the HMRC School and to the Augmentative Communication Service.

The HMRC MIDI music studio is equipped with a Roland U-20 sample-based keyboard; a Roland PAD-5 rhythm controller; a Roland CP-40 pitch-to-MIDI converter; a Roland RA-50 real-time arranger; a Roland CK-50 keyboard amplifier; a Macintosh Plus computer.

[555] Social Security Administration Voluntary Rehabilitation Demonstration Project

Alan C. Shafer

Social Security Administration, Office of Disability, Baltimore, MD 21235

Sponsor: *Social Security Administration*

Purpose—As mandated by Congress, this demonstration project will assess the advantages and disadvantages of permitting disabled disability insurance (title II) beneficiaries to select from among both public and private qualified vocational rehabilitation (VR) providers, and providers of VR services directed at enabling these beneficiaries to engage in substantial gainful activity (SGA). With the exception of fee-for-service reimbursement for conducting vocational evaluations and the development of an individualized written rehabilitation program, the reimbursement for rehabilitation services will follow current procedures (reimbursement of applicable expenses for success only).

Methodology—The specific design of the demonstration is in planning at this time.

Progress—An announcement published in the *Federal Register* on July 19, 1991, sought comments and statements of interest in this demonstration project. These responses were due August 30, 1991, at which

time they were analyzed and the sites for the demonstration project were to be determined. Planning for the shape of the demonstration project is occurring in concert with analysis of the responses to the *Federal Register* notice.

Results—The legislation calls for a final report on the demonstration project to be issued on April 1, 1994, with specific questions on its operation to be addressed in the report. Questions to be addressed include: the extent to which beneficiaries participate in the processes of selecting service providers, the various needs for rehabilitation, the extent to which nonState providers accept referrals and enter into third-party contracts, the likelihood of the beneficiaries to engage in SGA, the cost-effectiveness of permitting disabled beneficiaries to select their own providers of vocational services, and the feasibility of establishing a permanent nationwide program to allow disabled beneficiaries to choose their own qualified vocational rehabilitation provider.

[556] Social Security Pain Assessment Instruments Development Project

Karen S. Rucker, MD

Department of Medical Rehabilitation, Medical College of Virginia, Virginia Commonwealth University, Richmond, VA 23298-0677

Sponsor: *Social Security Administration*

Purpose—This project is piloting, testing for reliability and validity a series of proposed pain assessment instruments that can be routinely and uniformly used early in the disability determination process to identify chronic pain cases. In addition, the project is to develop techniques and propose additional methods in determining residual functional capacity (RFC) and the ability to work or return to work.

The instruments include: Claimant SSA Pain Instrument; Claimant's Significant Other SSA Pain Instrument; Physician's SSA Pain Instrument—Treating Physician; Physician's SSA Pain Instrument—Consulting Physician; Screening Instrument; Functional Capacity Assessment; and Integrated Summary Pain Report. By the end of this contract, SSA expects a final set of scientifically crafted and tested pain assessment instruments ready for the

testing of their efficiency and effectiveness within the SSA disability adjudication process and to identify potential persons for pain rehabilitation demonstrations.

Progress—The 33-month contract began July 1, 1990, and will terminate in March 1993. The pilot has been completed with a 3- and 6-month follow-up of the sample. Based on the findings, the instruments were revised and are being used for the Medical College of Virginia (MCV) Reliability and Validity Study's data collection currently in

progress. In 1992, a SSA Validity Replication Study will gather data from six national sites from SSA disability applicants.

Preliminary Results—The pilot indicated the instruments are not biased by age, gender, or race. They are easy to understand, consistent, but still too long. The major revisions in content and length are projected after the statistical results are available from the larger sample in the MCV Reliability and Validity Study.

[557] Project Network

Robert C. Cross

Social Security Administration, Office of Disability, Baltimore, MD 21235

Sponsor: Social Security Administration

Purpose—The Social Security Administration (SSA) is undertaking a series of four initiatives designed to test ways to increase opportunities for SSA clients with disabilities to receive the services they need to return to work. Collectively, we are calling these initiatives "Project NetWork." Project NetWork will provide access to the entire range of services necessary for a work attempt, including job placement and services on the job.

The four models to be tested are: 1) the SSA CM Model in which specially-trained SSA field office employees will coordinate a broad range of CM services; 2) the CM Outstationing Model which will test using State vocational rehabilitation agency counselors, under contract, to provide CM services; 3) the CM Contractor Model which will feature the use of private sector case managers under contract; and, 4) the Referral Specialist Model which involves the use of SSA employees to provide enhanced referral and support services.

For the past several years, SSA has conducted extensive research and outreach activities to find out why so few beneficiaries attempt to work. We have learned that:

- The current SSA service delivery system does not meet the needs of many SSDI/SSI beneficiaries who want to work because it does not provide sufficient access to rehabilitation and employment services;

- A strong outreach and marketing function is needed to tell the public about work incentives and the type of services and job placement opportunities that are available; and,
- Closer ties must be established with the many private and other public sector agencies. SSA should be actively involved in the coordination of services.

Project NetWork is based on two premises: 1) A CM concept that will provide ongoing continuity and coordination to the process of assisting people with disabilities toward gainful employment; and, 2) a resource management component that will ensure the availability of whatever services the individual needs to achieve goals.

Progress—SSA began with the CM model in three field offices in the Dallas and Fort Worth areas. This pilot went "live" in July 1991, with full-scale implementation beginning in February 1992. The remaining models were also scheduled to begin in 1991 as well.

Methodology—Applicants for SSA, including those concurrently applying for SSDI benefits, will receive information about the appropriate model when applying for benefits from the SSA claims representative. They will be invited to attend an interview conducted by a case manager/referral specialist

where they will be offered the opportunity to volunteer for the project. SSA will be mailing letters to all SSDI and SSI recipients in the service area of the pilot informing them of the program. A follow-up mailing will be made to all clients who did not respond to the initial mailing and have been collecting benefits for 2 to 5 years. Previous demonstration projects have indicated that this timeframe appears to be a good time in which individuals' impairments stabilize, after onset, and have a desire to return to work. Each prospective participant will receive a full explanation of the project, its goals and special features (waivers). Those who agree to

participate (volunteer) will be randomly assigned to treatment and control groups. Participants assigned to the control group will be eligible to use the waivers offered to all participants in the project.

Results/Implications—Each model will run for 2 years and will be independently evaluated to determine the success and impact of the model. The results of Project NetWork will provide SSA with ways to improve our nationwide service delivery system for people with disabilities and will open new opportunities for them to return to the workforce in meaningful roles.

[558] Social Security Administration Research Demonstration Program (RDP)

Alan C. Shafer

Social Security Administration, Baltimore, MD 21235

Sponsor: *Social Security Administration*

Purpose—The purpose of the Research Demonstration Program (RDP) is to conduct demonstration projects designed to stimulate, test, and coordinate effective approaches toward employment assistance as part of an innovative and systematic SSA-wide initiative for assisting beneficiaries with disabilities to enter the workforce or return to work. The focus of the program is to explore new methods for effective and efficient use of available vocational rehabilitation (VR) resources by bringing public and private sectors together. Most of the projects are oriented toward VR, but several address medical rehabilitation issues as well. Areas of demonstration include: early intervention, public awareness, rapid assessment, and improved communication about work incentives (WI), vocational/employment information, and development of new protocols for medical assessment.

Progress—SSA's first national RDP announcement was published on June 26, 1987, and was marketed to public as well as private rehabilitation providers. Since then, SSA has sponsored two additional RDP competitions, awarding a total of 120 grants to a wide variety of public and private rehabilitation providers. Over the past four years the RDP has

allowed SSA to interact with a wide variety of public and private agencies, and to develop a better understanding of the rehabilitation process as it applies to SSA's beneficiaries. Information from these projects will help SSA develop a systematic, efficient, and cost-effective rehabilitation/employment strategy capable of providing appropriate services at the most opportune time to those beneficiaries who do, in fact, desire to work.

Results—About 70 percent of awarded projects have ended and the findings are being analyzed by SSA. The remaining projects are in various stages of completion and are expected to end by September 30, 1992. A final report to Congress is due October 1, 1993.

SSA's grantee's early findings include:

- There is no best time to refer beneficiaries for rehabilitation services. Whereas some grantees have successfully used early intervention strategies, others reported success with beneficiaries who have been on the rolls 2 to 7 years. Evidence confirms that greater potential for rehabilitation lies with those individuals who have been on SSA's rolls 2 to 3 years than was previously expected.

- SSA's present VR screening criteria may be overlooking certain groups for which significant rehabilitation potential exists. These criteria will be carefully examined in the months to come.
- There is a need among VR professionals, parents, and Social Security Disability Insurance/Supplemental Security Income (SSDI/SSI) beneficiaries for reliable information on SSA WI in layman's language. As a result, several grantees have produced brochures to explain work incentives in language that beneficiaries, parents, advocacy groups, etc., can understand.
- Interagency collaboration on individual cases is required to access needed services from rehabilitation providers, employers, unions, and other. Private providers, if included in the system, can serve SSDI and SSI clients.

Future Plans/Implications—SSA will analyze the results of all projects in determining the future

direction of the disability program. Some of the initiatives may require legislative change to implement, but others can probably be implemented more quickly through changes in SSA's policies and procedures.

Many grantees tell us that "case management"—a process in which an individual or team monitors every facet of the service delivery process—is an effective strategy in rehabilitation programs. The information we gain from these grants is helping SSA define the case manager model for providing rehabilitation services to its beneficiaries, and has led to additional testing by SSA of case manager-based service models. SSA is also testing other ideas which might lead to improvement of rehabilitation service delivery.

SSA is required to prepare a report to Congress each year on the progress of the projects. These reports are available from the address above.

[559] Health Insurance Coverage of Disability Beneficiaries

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National Rehabilitation Hospital Research Center, Washington, DC 20010

Sponsor: Social Security Administration

Purpose—This study examined the disincentives to work among Social Security Disability Insurance (SSDI) beneficiaries who, if they obtain gainful employment, are at risk of losing Medicare benefits but may not be able to obtain comparable employment-based health insurance benefits.

The objectives of the study were to: 1) examine the relationship between health insurance coverage of SSDI beneficiaries and their decisions and capacities to seek, obtain, and maintain employment; and, 2) examine the private health insurance coverage available to SSDI beneficiaries, including gaps in coverage resulting from insurance exclusions, "pre-existing condition" clauses, and policy "riders."

Methodology—The study analyzed four existing data sets involving SSDI beneficiaries: 1) the 1982 New Beneficiary Survey, conducted on behalf of the Social Security Administration; 2) the Survey of Income and Program Participation, conducted by

the U.S. Census Bureau in stages since 1983; 3) the 1985 Louis Harris Survey of Disabled Americans, conducted for the International Center for the Disabled in cooperation with the National Council on the Handicapped; and, 4) the 1988 National Rehabilitation Hospital Survey of Persons with Severe Physical Disabilities. The staff also examined a variety of different private/public health insurance plans/options to determine the adequacy of coverage for persons with disabilities.

Results—This 2-year study was completed in September 1990; final results were submitted in January 1991. Results indicate that the greatest disincentives are for persons who return to part-time work, as opposed to full-time work. Part-time workers are less likely to obtain the private health insurance they need when they lose public coverage through Medicare or Medicaid.

In the analysis of coverage adequacy of existing health insurance options, results indicate that per-

sons with disability are likely to require a continuum of services which extend beyond the coverage limitations of private programs. These services may include home health care, personal assistance, durable medical equipment, and similar services. Generally speaking, most private group plans provide protection that is equal to, or better than, that offered through the Medicare program. However, few private plans match the scope of coverage

provided through the Medicaid program, which is more oriented to the needs of persons with chronic conditions.

Recent Publications Resulting from This Research

The Health Insurance Status of Working-Age Persons with Physical Disabilities: Results of the NRH Survey. Burns TJ, Batavia AI, DeJong G, Inquiry (Summer):187-193, 1991.

[560] Transportation Information Base: People with Disabilities

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Hickling Corporation, Ottawa, Ontario K1R 7S8 Canada

Sponsor: Transport Canada

Purpose—The Transportation Information Base (TIB) characterizes the transportation and socioeconomic patterns of Canadians with disabilities. Consumer groups, governments, researchers, carriers, and industry may use the TIB to: analyze the transportation requirements of various groups of people with disabilities; develop policy; and ultimately improve transportation systems for people with disabilities.

Progress/Methodology—Hickling Corporation has developed North America's most comprehensive database dealing with transportation and disability. It is an amalgamation of data from several surveys—primarily the Health and Activity Limitation Survey (HALS) conducted by Statistics Canada after the 1986 census—and previous Hickling studies. The scope of the information makes it the largest database of its type in the world. A model which predicts the number of transportation-disabled (TD) people by geography has been developed.

The information base profiles:

- **Geographic areas:** provinces, regions, cities, rural areas
- **Disability groups:** mobility impaired, sensory impaired, cognitively impaired, wheelchair users, etc.
- **TD groups:** homebound, TD-local, TD-intercity, TD-personal vehicles, TD-others

- **Socio-economic characteristics:** age, sex, income, employment, education
- **Comparisons:** to the general population, and predictions of future populations.
- **Modes of transportation:** long distance (air, rail, bus); short distance (bus, specialized transit, taxi); and personal vehicles (cars and vans)
- **Travel patterns:** need, availability, usage, trouble with use, type of trouble, need for assistants.

The primary source of data is Statistics Canada's HALS. Hickling has supplemented HALS with data from other surveys and studies performed in North America over the last decade, and with in-depth statistical analysis of the survey data.

Results—Hickling has produced a report using numerous runs of the Information Base which summarizes the socio-economic and travel characteristics of Canadians with disabilities. The report also provides an assessment of current federal policies in this field, based on these market data.

Future Plans/Implications—Current plans are for the Information Base to be housed in the Transport Canada premises in Montreal. Alternatively, Hickling or some other organization may house the Information Base, and operate it on behalf of Transport Canada. In either case, the Information Base will be made available to the public on a cost-recovery basis.

Section II

VA Sponsor Index with Selected Program Summaries

Department of Veterans Affairs

Rehabilitation Research and Development Service
810 Vermont Avenue, N.W.
Washington, DC 20420

James L. Green, MD, Acting Deputy Associate Deputy, Chief Medical Director for Rehabilitation and Prosthetics, and Acting Director, Rehabilitation Research and Development Service, Office of Clinical Affairs, Department of Veterans Affairs, Washington, DC

The mission of the Rehabilitation Research and Development Service program is to improve the quality of life of disabled veterans by making them more functionally independent. This mission is advanced through ongoing research projects in such priority areas as prosthetics/amputation, spinal cord injury, and sensory aids. Areas of special emphasis include aging, physical fitness, and psychosocial rehabilitation (e.g., dementia, schizophrenia, Alzheimer's disease, etc.).

In the areas of prosthetics, amputation, and orthotics, VA-sponsored researchers are continuing to test new materials and using computer technology such as CAD/CAM to develop a new generation of artificial limbs. For spinal cord injuries, the use of robotics continues to be studied, as does the possibility that computer-controlled electrical stimulation can be used to restore function to paralyzed limbs. Research projects in the area of sensory aids include the continuing development of advanced mobility aids for visually impaired people, digital hearing aids for those with hearing impairment, and various studies on treatment strategies and communication systems for aphasic individuals.

The Department of Veterans Affairs Rehabilitation Research and Development Service sponsors a national program to review proposals submitted by researchers in the rehabilitation field. The Scientific Review and Evaluation Board for Rehabilitation Research and Development and ad hoc members assess proposals for their scientific and technical merit, budgetary needs, and time requirements. In 1991, the Board reviewed 80 regular proposals. There were 35 research projects approved in the four general priority areas: 1) prosthetics/amputation/orthotics; 2) communication, sensory, and cognitive aids; 3) spinal injury and related neurological disorders; and, 4) aging. Sixteen pilot projects were approved to run for 1 year. Pilot projects are designed to test the feasibility of

developing data, a technique, or a procedure prior to undertaking a regular study.

VA Prosthetics Research and Development Center
103 South Gay Street
Baltimore, MD 21202-4051

Three units comprise the VA Prosthetics Research and Development Center: Office of Technology Transfer, Prosthetics Assessment and Information Center, and Rehabilitation Evaluation Unit.

Office of Technology Transfer
Husher L. Harris, Director (Acting)

The Office of Technology (OTT) is responsible for the dissemination of information on completed and ongoing results of rehabilitation research and engineering developments. OTT publishes the *Journal of Rehabilitation Research and Development (JRRD)*, *Rehabilitation R&D Progress Reports*, and *Clinical Supplements to JRRD*.

The *Journal of Rehabilitation Research and Development* is a scientific, technical, and engineering quarterly publishing original research in rehabilitation. Supplements based on need and interest in the areas covered by *JRRD* and presented in a format appropriate for the clinician/practitioner are also published. The annual *Rehabilitation R&D Progress Reports* is a compilation of summaries by investigators on the status of their current research. Portions of OTT publications are available electronically through the VA Rehabilitation Database on CompuServe.

Prosthetics Assessment and Information Center
Ronald I. Lipskin, Director

The mission of the Prosthetics Assessment and Information Center (PAIC) is to evaluate commercial rehabilitation products, develop product standards on safety and performance, facilitate the delivery of rehabilitation technology directly to disabled veterans and the clinicians who care for them, and report this information to clinical and procurement officials throughout the VA system.

During Fiscal Year 1991, PAIC completed evaluations of 47 commercial products. Reports were submitted to the VA Marketing Center for formal action through the Prosthetic Technology Evaluation Committee (PTEC) in

the Department of Veterans Affairs Central Office.

Standards development activities, on manual and powered wheelchairs, focus on identifying levels of performance acceptability for VA procurement purposes and validation of testing procedures as defined in the documents prepared by RESNA for submission to the American National Standards Institute (ANSI). Technical personnel are cooperating with automotive adaptive equipment committees, coordinated by the Society of Automotive Engineers (SAE), to develop product standards on adaptive aids.

The Clinical Interface Program (CIP) continues to provide *rehabilitation technology* to the veterans and clinicians within and *outside* the Baltimore and Washington, DC areas.

A Pilot Study on Technology for Nursing Home Care Units was completed and published; it is available through this office.

Rehabilitation Research and Development Evaluation Unit

Saleem J. Sheredos, Director

The mission of the VA Rehabilitation Research and Development Evaluation Unit (REU) is to oversee the introduction of, promote the use of, and foster the availability of new devices and techniques to optimize the rehabilitation of physically challenged veterans.

REU's goals are to: 1) screen ongoing rehabilitation research and development, primarily sponsored by the Department of Veterans Affairs Rehabilitation Research and Development Service (RRDS), to identify products or techniques that are ready for transfer from research and development to clinical application, for which the VA has an identified need; 2) coordinate clinical application studies away from the R&D arena on the selected products and techniques to affirm their application in treatment programs; 3) foster the commercial availability of successful products by helping to overcome the barriers faced by potential manufacturers; and, 4) widely disseminate clinically useful information to professionals who effect the rehabilitation of disabled veterans.

When a development (technique or device) is identified as completed, a Request for Evaluation (RFE) is prepared in accordance with VA Circular 10-87-32 and forwarded to the Director, REU, at 103 South Gay St., Baltimore, MD 21202. The RFE must be sent over the signatures of the R&D principal investigator(s) (PI), the Associate Chief of Staff for Research and Development (ACOS/R&D), and the Director of the VA Medical Center funded for the R&D effort.

An addendum to this procedure (called an RFE INTENT) is currently being tested. This document is intended for use when the development is within 12 months of completion. It is prepared according to the same requirements as the RFE, except that it requires only the PI's signature, with a copy going to the ACOS/R&D. This procedure was initiated to aid the timely review and budget plans for the potential field

study which should lead to a commercial product or an effective procedure for clinical use.

Once the RFE is received, it is nominally reviewed by three experts on the readiness and current value for clinical application, which leads to recommendations for a field study, or the need for further development, or project termination.

For an approved RFE, a field study is designed and implemented by the Director, REU, as the evaluation's PI who collaborates with the R&D PI(s) and the appropriate VA Central Office (VACO) Service Director(s), with approval of the Director, RRDS. Field-participating investigators are designated who coordinate the local clinical trials. The Research and Development PI is a consultant (generally at no cost) to the study, while VACO Service Directors are administrative collaborators in accomplishing the study.

REU coordinates the evaluation, collects the data, performs data analysis, issues progress reports (using SPSS software), and prepares the final report with specific recommendations.

During 1991, REU worked on the following projects:

Ongoing Projects

1. Advanced Body-Powered Prosthetic Arm
2. APL/Dankmeyer A/E Powered Prosthesis
3. Back Analysis System
4. Beta Test Wheelchair Standards Database
5. Cosmetic Cover for Lower Extremity
6. Desktop Vocational Assistant Robot System
7. Hypobaric Suction Sleeve for B/K Prosthesis
8. Modular Electro-Mechanical Lock Actuator for A/E Prosthesis
9. A Variety of Digitizers for Lower Limb Prosthetic CAD/CAM
10. Rectal Probe Electro-Ejaculation Battery-Powered Unit
11. Ultrasonic Head-Controlled Powered Wheelchair
12. VA-Seattle B/K prosthesis modular components and the first VA Regional AFMA (CAD/CAM)
13. Wheelchair Aerobic Fitness Trainers

Completed Projects

1. CP Skin for B/K Prosthesis
2. Handbike
3. Synergetic Prehensor

The Rehabilitation Research and Development Center Edward Hines, Jr., Hospital, Department of Veterans Affairs

Hines, IL 60141

John Trimble, PhD, Director

Fiscal Year 1991 was an exciting and productive year for the VA Hines Rehabilitation Research and Development Center. Our reorganized research program has proven effective in creating new opportunities for studies in the areas of musculoskeletal disorders, rehabilitative neurosciences, and applied exercise science and health promotion.

The musculoskeletal disorders research section has made considerable progress in the area of characterizing the dynamics of motor tasks. This work has led to strategic alliances with major healthcare equipment manufacturers and hospital alliances.

The rehabilitative neurosciences research section has also made excellent progress, especially in the areas of neural regeneration and restoration of bladder function. Our studies on spinal cord regeneration have led to significant new uses for advanced materials and research partnerships with major, private-sector materials research laboratories. Our work on restoration of bladder function has attracted the attention of clinicians and medical equipment manufacturers who are eager to see our research results put to clinical use.

The applied exercise science section has also made significant progress in transferring its research results. The tests developed by researchers in this group have been used on a regular basis to diagnose coronary artery disease in people with mobility limitations. We are hoping that their innovations will soon set the "gold standard" for this type of testing.

Our newly developed extramural programs have also begun to produce results. Projects with the Harry G. Armstrong Aerospace Medical Research Laboratory at Wright-Patterson Air Force Base have yielded new algorithms for joystick controllers and new techniques for displaying three-dimensional sound. Studies with Baxter Healthcare Corporation and Isotechnologies, Inc., have led to techniques that may improve the clinician's ability to diagnose low back disorders or track their treatment. Work with Hollister, Inc. has resulted in designs for new devices for controlling micturition dysfunction. All of these projects take full advantage of the Department of Veterans Affairs' initiatives in developing public-private partnerships under the Federal Technology Transfer Act of 1986.

Our satellite research and development program at the University of Illinois at Urbana-Champaign has also begun to bear fruit. Thirteen pilot projects have been funded and several have progressed to the point where they have been submitted to the Department of Veterans Affairs for continuing funding.

Our technology development program has spawned over a dozen senior design projects in the Department of Mechanical and Industrial Engineering at the University of Illinois at Urbana-Champaign. All of these projects have resulted in tangible products and at least one has developed into a commercially viable concept.

In summary, the Rehabilitation R&D Center at VA Hines Hospital continues to be a significant resource for research on disability-related problems and the development and commercialization of enabling technologies.

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Rehabilitation Research and Development Center
Department of Veterans Affairs Medical Center
Palo Alto, CA 94304-1200
Felix E. Zajac, PhD, Director

The Palo Alto Rehabilitation Research and Development (RR&D) Center, in affiliation with the Schools of Engineering and Medicine of Stanford University, is dedicated to developing new state-of-the-art technological aids and treatments for disabled veterans. To accomplish this objective, we perform basic and applied research essential to the development of new aids and treatments, design and develop rehabilitation devices and methods, and foster the growth of the rehabilitation field through education.

The mission of the RR&D Center is to improve the quality of life of veterans with limb disabilities by designing new devices and methodologies. We are accomplishing this mission by working toward three goals: 1) preserving limb function, in face of existing or threatening limb disabilities; 2) restoring function that is impaired owing to limb disabilities; and, 3) replacing function lost by limb disabilities. Accomplishing these goals improves the quality of life of limb-disabled veterans by increasing their independence, upgrading their competence in activities of daily living, and enlarging possibilities for their occupational and vocational rehabilitation.

The following two examples illustrate the importance of limb function as a focus of concentration. First, traumatic injuries often lead to disabilities in multiple limbs (quadriplegia), single limbs (amputations), or partial limbs (nerve, tendon, and bone damage). Rehabilitation may begin with surgical intervention (nerve repair, tendon transfer, joint replacement) and may continue with techniques such as functional neuromuscular stimulation. When restoration is suboptimal, application of robotics may replace lost function. Second, elderly patients frequently have multiple disabilities including vision impairment, nerve damage, amputation, and arthritis. In such a patient, *preservation* of remaining function by prevention of falls, *restoration* of function

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through joint prostheses, and *replacement* of function by use of tactile computer interfaces, will all contribute to increased independence and better quality of life.

The RR&D Center is organized around three Sections of investigators: the Neuromuscular Systems (NMS), Orthopaedic Biomechanics (OBM), and Human Machine Integration (HMI) Sections. These Sections work at times separately and at other times together to accomplish subgoals associated with each of the three goals (i.e., the preservation, restoration, and replacement of limb function in disabled veterans). To assure that new rehabilitation devices and methodologies reach the disabled veteran and rehabilitation clinic as soon as possible, the Technology Transfer Section conducts an energetic program for the continual transfer of products and techniques developed by the three investigator Sections (HMI, NMS, OBM). The Technical Support and Administrative Support Sections support the research and development projects and the technology transfer activities by assuring the efficient operation of the RR&D Center in meeting VA regulations and providing liaison with the Palo Alto VA Medical Center and the Department of Veterans Affairs Central Office operational services (e.g., Fiscal, Supply, Research Office, RR&D Service).

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Atlanta Rehabilitation Research and Development Center

**Department of Veterans Affairs Medical Center
Decatur, GA 30033**

Franklyn K. Coombs, Director

The Atlanta Rehabilitation Research and Development (Rehab R&D) Center has a unifying theme, or focus, on

aging. The aging theme represented the majority of the research at the Atlanta Center. However, the Center also conducted research in the other priority areas designated by the Rehab R&D program. The Atlanta Center's Five-Year Plan on Aging supports activities in five research areas addressing the problems and needs of aging and disabled veterans. The research areas are: 1) Musculoskeletal; 2) Sensorimotor; 3) Cognition; 4) Wellness and Health Maintenance; and, 5) Safety and Mobility. The Center supports basic and applied research, product development, technology transfer, and educational projects in these five areas.

To address the timely and important issues in aging, the Atlanta Rehab R&D Center has established a two-part mission to:

1. understand, by knowledge gained through research, the problems, capabilities, and needs of elderly and disabled veterans that impact on their functional independence, wellness, and quality of life; and,

2. apply those understandings to the development of concepts, techniques, and devices that further functional independence, wellness, and quality of life for elderly and disabled veterans.

To accomplish this mission, the Center conducts research into problems associated with the loss of independence, mobility, cognition, and health status of older people. Further, the accomplishment of this mission will include the development of new or unique concepts, techniques, and devices for rehabilitation. This may include the collection and analysis of normative data on older people's deterioration of function. An important component of the Center Plan is the dissemination and utilization of the research and development results in clinical or applied practice in the community.

An important strength of the Center is its multidisciplinary staff, which allows simultaneous research on several facets of problem areas in aging. The Center staff consisted of 48 people, including 4 MDs, 16 PhDs, and 7 persons with a master's degree. An additional MD and 10 PhDs were supported by Intergovernmental Personnel Agreements (IPAs) with the affiliated universities. The Center is affiliated with Emory University School of Medicine and Georgia Institute of Technology (Georgia Tech). In 1991, the Atlanta Center expanded its affiliations to include Clemson University, Department of Bioengineering, and Georgia State University, Department of Gerontology. All of the professional staff have appointments with one or more of the affiliated universities.

The Atlanta Rehab R&D Center supported 34 projects in FY 1991. This total consisted of 21 merit approved and funded projects and 13 locally approved and funded projects. Five additional VA merit projects have been approved for funding in FY 1992. Three of the merit projects were NIH funded and one was NIDRR funded. The locally approved projects received funds from the Hilton Foundation, the Atlanta Research and Education Foundation, the American Legion, and the private sector.

To support the information dissemination and educa-

tional goals, the Center conducts programs in several areas. Three training videos were produced with designated funds from the extramural sources, which are available commercially from the sponsoring organizations. The Rehab R&D Center staff published 22 refereed journal articles, 35 abstracts, and 5 book chapters in FY 1991. The Center staff made 9 invited lectures and 22 conference presentations. Four of the invited lectures were presented at international conferences, where the invitee's expenses were paid by the sponsors. Serving on editorial boards of refereed journals, the Center staff reviewed 794 submitted articles and critically reviewed five books. In support of professional activities, the Center staff were chairpersons for 14 different sessions at professional conferences and reviewed 13 abstracts for professional conferences. Seven of the staff hold offices in professional organizations.

Three members of the senior staff serve on the VA Medical Center Research and Development Committee, and reviewed more than 180 merit applications within the VA/Emory research community. In addition, the Rehab R&D Center supported 3 doctoral candidates and 10 master's degree candidates. These students either conducted part of their research at the Center, or in some cases with Center resources, or Center staff served on the graduate committee.

The Center resources are used to: conduct pilot studies that develop merit review applications; support key research personnel; provide common equipment; and, support the administrative staff.

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